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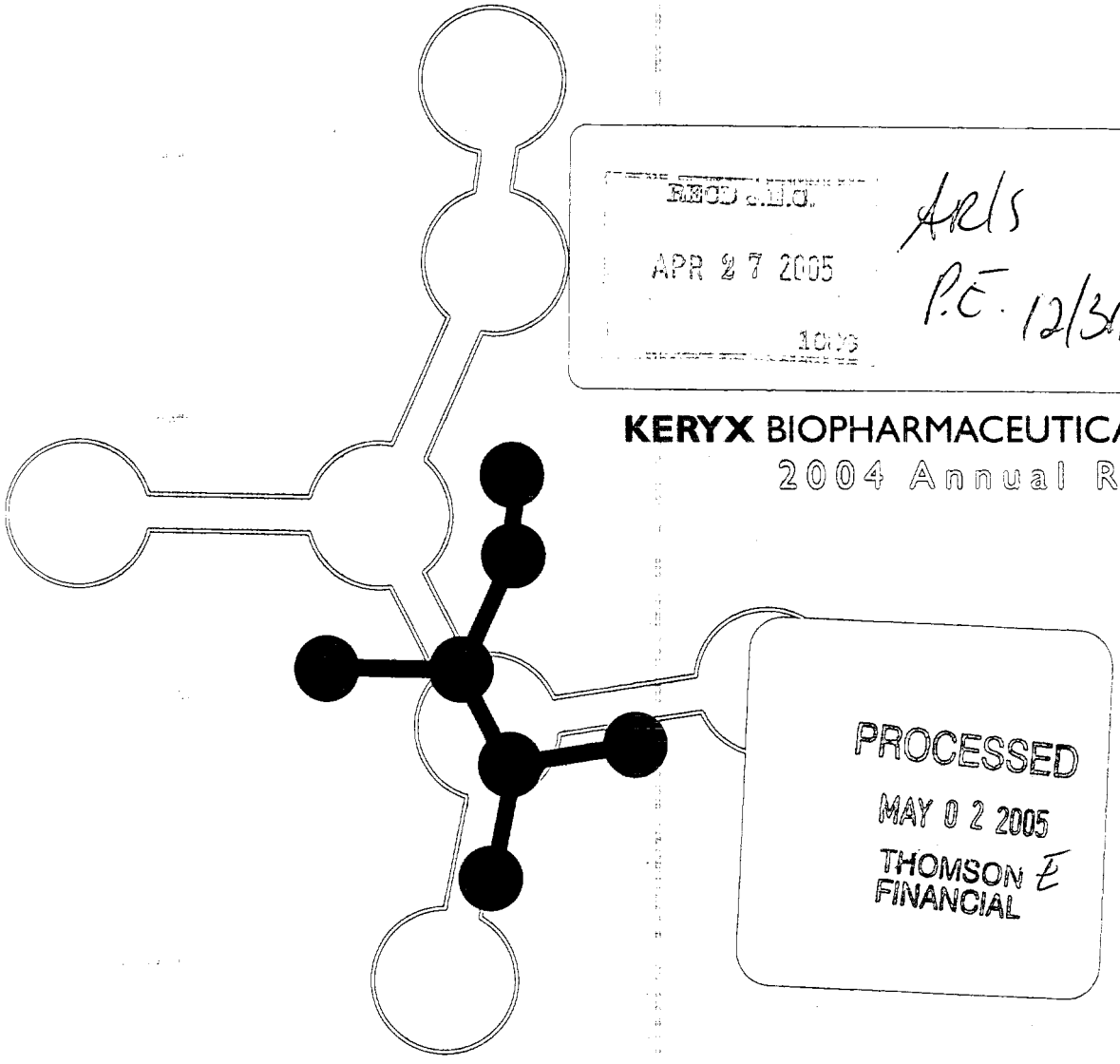
KERYX BIOPHARMACEUTICALS, INC.

2004 Annual Report



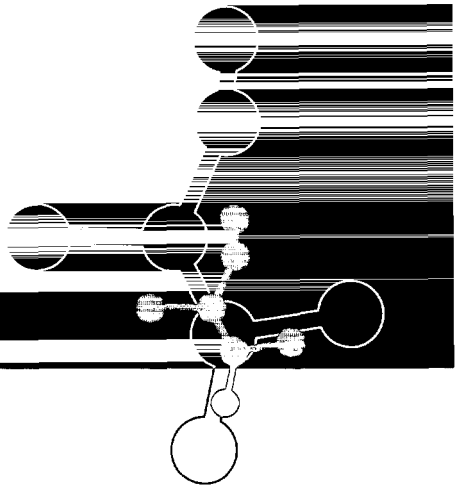
Keryx Biopharmaceuticals, Inc. Mission Statement:

Keryx is a biopharmaceutical company focused on acquiring, developing and commercializing novel treatments for life-threatening diseases, including diabetes and cancer.

Key Highlights

- Completion of patient recruitment into Phase II component of KRX-101 Phase II/III US-based clinical program
- Announcement of results of Data Safety Monitoring Committee and Collaborative Study Group safety and efficacy review of first interim analysis from Phase II/III Clinical Program for KRX-101, pursuant to which CSG recommended that the program proceed into Phase III
- Initiation of Phase II Keryx-sponsored single agent and combination studies for KRX-0401 (Perifosine)
- Establishment of several research collaborations with prominent universities for KRX-101 and KRX-0401 under our Scientific Open Access Research (SOAR) programs
- Completion of financing round raising $32 million with top-tier institutional biotechnology investors
- Enhancement of our analyst research coverage

This Annual Report contains forward–looking statements that reflect our current expectations regarding future events. While these statements reflect our best current judgment, they are subject to risks and uncertainties, certain of which may be beyond our control. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We use the words "believes", "expects", "intends" and similar expressions to help identify forward-looking statements. There are a number of factors that may cause our actual results to differ materially from those indicated or implied in the forward-looking statements. These factors include, without limitation, those set forth in the "Risk Factors" section of our Annual Report on Form 10-K and our quarterly reports on Forms 10-Q, which we have filed with the SEC. We disclaim any obligation or intention to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



2004: BUILDING MOMENTUM

Dear Keryx shareholders,

2004 was a year of tremendous progress and achievement at Keryx. Capitalizing on the momentum from 2003, we continued with our commitment to the dynamic growth of the Company and the timely execution of our aggressive business plan. We have worked extremely hard to advance both of our lead product candidates, KRX-101 in Phase II/III for the treatment of diabetic nephropathy and KRX-0401 in Phase II for the treatment of several tumor types. With these two promising, later stage, clinical compounds, and with several other programs in earlier clinical- and pre-clinical development, we believe we have assembled one of the most robust drug pipelines in the mid-cap biotechnology sector.

KRX-101: US-BASED PHASE II/III CLINICAL PROGRAM

Working closely with the Collaborative Study Group (CSG), in the fourth quarter of 2004, we were pleased to announce the completion of patient enrollment into the Phase II portion of our KRX-101 Phase II/III clinical program. A few months later, in early January 2005, we reported that an independent Data and Safety Monitoring Committee (DSMC) and the leadership of the CSG, conducted an interim analysis of the Phase II data. Based on this interim review of both safety and efficacy, the CSG recommended that we proceed as planned into the Phase III component of the Phase II/III program. We believe that completion of patient enrollment and the recommendation to proceed into Phase III are the Company's most critical milestones to date, and we owe a debt of gratitude to the CSG for their steadfast dedication to this program. The Company continues to view the support and partnership of the CSG as an important validation of the potential of KRX-101 as a treatment for this devastating disease.

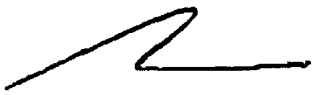
KRX-0401: INITIATION OF CORPORATE SPONSORED CLINICAL PROGRAM

In the second half of 2004, the Company announced the initiation of its corporate-sponsored clinical program for KRX-0401. To date, the Company has initiated a variety of studies designed to evaluate the safety, tolerability and preliminary efficacy of KRX-0401 in multiple forms of cancer, both as a single agent and in combination with other anti-cancer treatments. With its ability to target Akt, a protein critical for cancer cell resistance and growth, and now with three confirmed partial responses in Sarcoma indicating evidence of potential activity as a single-agent, we believe that KRX-0401 represents one of the most exciting novel targeted therapies in clinical development today for the treatment of cancer. We plan to spend a great deal of time and energy over the coming year demonstrating the utility of this novel anti-cancer drug as a single-agent in selected tumor types, as well as exploiting its Akt and other signaling effects to enhance the activity of other agents when used in combination.

POISED FOR SUCCESS

With the pending commencement of our pivotal program for KRX-101 in diabetic kidney disease and a robust Phase II program underway for KRX-0401 in multiple forms of cancer, we believe Keryx is poised for great success over the coming years.

Finally, on behalf of the Company and its Board of Directors, I would like to take this opportunity to sincerely thank our loyal shareholders for their continued commitment. With 2005 upon us, we are continuing in our quest to build sustainable shareholder value in the Company by conducting multiple clinical trials for our product candidates and by enhancing our product pipeline through additional product acquisitions. We look forward to your ongoing support as we continue to set the bar high and deliver on our promises in the hopes of exceeding your expectations.



Michael S. Weiss

Chairman and Chief Executive Officer

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004.

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission File Number 000-30929

KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	13-4087132
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
750 Lexington Avenue New York, New York	10022
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (212) 531-5965

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, Par Value $0.001 Per Share

(Title of Class)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [x] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes [x] No [ ]

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was $305,130,826 as of June 30, 2004, based on the closing sale price of such stock as reported on the Nasdaq National Market.

There were 31,504,180 shares of the registrant's common stock outstanding as of March 4, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2005 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

KERYX BIOPHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

This Annual Report on Form 10-K contains trademarks and trade names of Keryx Biopharmaceuticals, Inc., including our name and logo.

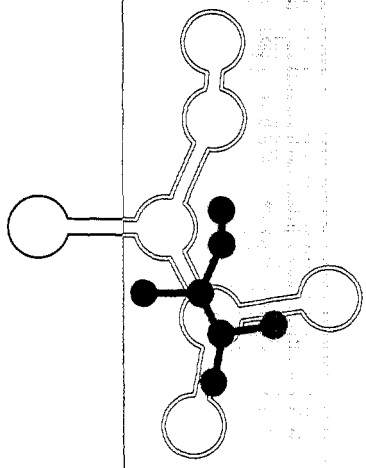
SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," and similar expressions are intended to identify such forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Business—Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, as well as factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, those relating to:

- our expectations for increases or decreases in expenses;
- our expectations for the development, manufacturing, and approval of KRX-101, KRX-0401, and our additional product candidates or any other products we may acquire or in-license;
- our expectations for incurring additional capital expenditures to expand our research and development capabilities;
- our expectations for generating revenue or becoming profitable on a sustained basis;
- our expectations or ability to enter into marketing and other partnership agreements;
- our expectations or ability to enter into product acquisition and in-licensing transactions;
- our estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating and capital requirements;
- our expected losses; and
- our expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.



PART I

Unless the context requires otherwise, references in this report to "Keryx," the "Company," "we," "us" and "our" refer to Keryx Biopharmaceuticals, Inc., its predecessor company and our respective subsidiaries.

ITEM 1. BUSINESS.

Overview

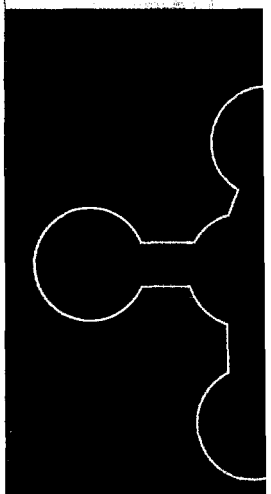
We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. We have two product candidates in the later stages of clinical development: sulodexide, or KRX-101, for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes, and perifosine, or KRX-0401, for the treatment of multiple forms of cancer.

Our lead compound under development is KRX-101, to which we have an exclusive license in North America, Japan and certain other markets. A randomized, double-blind, placebo-controlled, Phase II study of the use of sulodexide for treatment of diabetic nephropathy was conducted in 223 patients in Europe, and the results of this study were published in the June 2002 issue of the Journal of the American Society of Nephrology. The results of this Phase II study showed a dose-dependent reduction in proteinuria, or pathological urinary albumin excretion rates. In 2001, the Food and Drug Administration, or FDA, granted KRX-101 "Fast-Track" designation for the treatment of diabetic nephropathy, and, in 2002, we announced that the FDA had agreed, in principle, to permit us to avail ourselves of the accelerated approval process under subpart H of the FDA's regulations governing applications for the approval to market a new drug.

In the third quarter of 2003, we announced that the Collaborative Study Group, or CSG, the world's largest standing renal clinical trial group comprised of academic and tertiary nephrology care centers, would conduct the U.S.-based Phase II/III clinical program for KRX-101 for the treatment of diabetic nephropathy. The CSG has conducted multiple large-scale clinical trials resulting in over 40 publications in peer-reviewed journals. In addition, the CSG conducted the pivotal studies for two of the three drugs that are currently approved for treatment of diabetic nephropathy. In the fourth quarter of 2003, we initiated the Phase II portion of our Phase II/III clinical program for KRX-101, and in the third quarter of 2004, we completed the target enrollment for this Phase II portion of the clinical program.

In January 2005, we announced that the CSG recommended that we proceed to the Phase III portion of our Phase II/III clinical program of KRX-101, as planned. This recommendation was based on the completion, by an independent Data Safety Monitoring Committee, or DSMC, on January 4, 2005, of a safety evaluation of the first interim analysis from the approximately 150-patient, randomized, double-blind, placebo-controlled Phase II clinical trial of KRX-101, and an efficacy assessment of the same data set conducted by the CSG.

Pursuant to this recommendation, and subject to the successful finalization of our clinical plan with the FDA, we expect to commence our pivotal program, including both Phase III and Phase IV studies for KRX-101, in the first half of 2005. The clinical plan to support a new drug application, or NDA, for KRX-101 under Subpart H (accelerated approval) as discussed with the FDA consists of: (i) a Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria; (ii) supportive data from previous clinical studies; and (iii) substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. As part of our commitment to the FDA, we plan to commence the Phase IV trial at approximately the same time as the start of the Phase III trial.



In the first quarter of 2004, we completed the acquisition of ACCESS Oncology, Inc., or ACCESS Oncology, a privately-held, cancer-focused biotechnology company. The acquired drug portfolio includes three clinical stage oncology compounds, designated as KRX-0401, KRX-0402 and KRX-0403.

KRX-0401 is a novel, first-in-class, oral signal transduction modifier that inhibits the Akt pathway and other important pathways. It has demonstrated preliminary single agent anti-tumor activity. KRX-0401 is currently in a Phase II clinical program in which it is under evaluation as a single agent as well as in combination with other anti-cancer treatments for multiple forms of cancer. The National Cancer Institute, or NCI, a department of the National Institutes of Health, or NIH, has completed a number of Phase II clinical trials studying KRX-0401 as a single agent, conducted and funded by the NCI under a Cooperative Research and Development Agreement, or CRADA, arrangement with us. To our knowledge, the NCI and its collaborators have presented data from three of their Phase II studies through the date hereof, including from Phase II studies involving sarcoma, head and neck and breast cancers. Findings from these studies led the investigators to conclude that the drug was safe and well-tolerated at the Phase II dose utilized. In the sarcoma study, the investigators reported a partial response (greater than 50% decrease in tumor mass) as well as several disease stabilizations. With the responses seen in the Phase I trials, there are now three sarcoma patients with durable partial responses. On the Phase II breast cancer study, the investigators scored 3 of 15 evaluable patients as having stable disease, one of which was classified as a mixed responder.

During the second quarter of 2004, we announced the initiation of the Keryx-sponsored Phase II program for KRX-0401. To date we have initiated several trials under this program. The first is a multi-center study that will evaluate the safety and efficacy of KRX-0401 as a single agent administered weekly to patients with non-small cell lung cancer, or NSCLC, who have progressed despite standard therapy. We have also initiated additional multi-center trials evaluating KRX-0401 in combination with gemcitabine (Gemzar®), paclitaxel (Taxol®) and docetaxel (Taxotere®), all common forms of chemotherapy used to treat multiple tumor types. Recently, we started an "all-comers" Phase II clinical trial evaluating KRX-0401 as a single-agent administered either weekly or daily in a variety of tumor types.

Our cancer portfolio also includes KRX-0402, an inhibitor of DNA repair, which is also being studied by the NCI under a CRADA arrangement in multiple clinical trials. In addition, the portfolio includes KRX-0403, which is a novel spindle poison, or type of chemotherapy commonly used. We are currently evaluating whether we will continue development of KRX-0403.

As a part of the acquisition of ACCESS Oncology, we acquired the Online Collaborative Oncology Group, Inc., or OCOG, a subsidiary of ACCESS Oncology which provides clinical trial management and site recruitment services to us as well as other biotechnology and pharmaceutical companies.

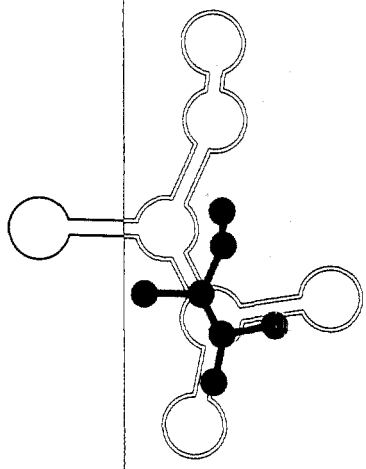
During 2004 and in the first quarter of 2005, we in-licensed two pre-clinical compounds in accordance with our acquisition and in-licensing strategy, which have been designated as KRX-0404 and KRX-0501, respectively. These compounds are in the areas of oncology and neurology, respectively.

To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

Our Strategy

We are focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Under our strategy, we currently plan to:

- launch our pivotal program for KRX-101, including our Phase III and Phase IV trials;
- continue our Keryx-sponsored Phase II clinical trial program for KRX-0401 exploring the use of KRX-0401 as a single-agent and in combination with other anti-cancer therapies in multiple cancer types;



- support additional scientific collaborations for KRX-101 and KRX-0401;
- conduct additional pre-clinical and clinical trials for our other product candidates; and
- seek to in-license or acquire additional clinical-stage compounds.

Corporate Information

We were incorporated in Delaware in October 1998. We commenced operations in November 1999, following our acquisition of substantially all of the assets and certain of the liabilities of Partec Ltd., our predecessor company that began its operations in January 1997. Our executive offices are located at 750 Lexington Avenue, New York, New York 10022. Our telephone number is 212-531-5965 and our e-mail address is info@keryx.com.

We maintain a website with the address www.keryx.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report.

PRODUCTS UNDER DEVELOPMENT

KRX-101

Overview

We have obtained a license to develop sulodexide, or KRX-101, to treat diabetic nephropathy and other conditions. Diabetic nephropathy is a long-term complication of diabetes in which the kidneys are progressively damaged. Sulodexide, our lead drug candidate, is a glycosaminoglycan compound with structural similarities to the broad family of marketed heparins and low molecular weight heparins. Specifically, sulodexide is comprised of heparan sulfate, also referred to as fast-moving heparin, dermatan sulfate and slow-moving heparin. This drug has been marketed in a number of European, Asian and South American countries for many years by our licensor for certain cardiovascular conditions and has a well established safety profile at the doses used for such indications. Additionally, it has been demonstrated in multiple clinical trials conducted in Europe, including a randomized, double-blind, placebo-controlled Phase II study, that KRX-101 can reduce urinary protein excretion in patients with diabetic nephropathy. In the fourth quarter of 2003, we announced the initiation of our KRX-101 U.S.-based Phase II/III clinical program for the treatment of diabetic nephropathy. In the third quarter of 2004, we completed the target enrollment for the Phase II portion of this clinical program. This trial is being conducted by the CSG. In January 2005, we announced that the CSG, based on a safety and efficacy analysis of the interim Phase II data conducted by an independent DSMC and the CSG, respectively, recommended that we proceed to the Phase III portion of our Phase II/III clinical program of KRX-101 for the treatment of diabetic nephropathy, as planned.

We plan to develop sulodexide in the United States, and possibly other countries where we have exclusive rights under our license, for the treatment of diabetic nephropathy and potentially for other indications.

Market Opportunity

According to the American Diabetes Association, or ADA, there are 18.2 million people in the United States, or approximately 6.3% of the population, who have diabetes. Of this population, approximately 13 million have been diagnosed with the disease, of whom approximately 90-95% have been diagnosed with diabetes mellitus, type 2, referred to as DM2. DM2 results from the combination of insulin deficiency and the body's relative insensitivity to the insulin present, as opposed to DM1, in which severe insulin deficiency results from destruction of the

insulin-producing beta cells of the pancreas. Moreover, an August 2003 study published by Datamonitor estimates that approximately 50% of all diabetics in the U.S., or approximately 9 million people, have diabetic nephropathy. Diabetes is the most common cause of End Stage Renal Disease, or ESRD, in the United States and in many other developed nations and represents approximately 45% of all new cases of ESRD in the United States. Despite advances in clinical care, including improvements in glycemic or blood sugar control and blood pressure control, the number of DM1- and DM2-related cases of ESRD continues to rise. In particular, the incidence of DM2-related ESRD is rapidly increasing. Less than 20% of diabetics on dialysis in the United States survive for five years, making the mortality of end-stage renal failure in this group higher than most forms of cancer. Unfortunately, renal transplantation is an option for less than 20% of diabetics with ESRD, as compared to 40-50% of non-diabetics, principally due to age and concomitant vascular disease. Despite recent advances, diabetic nephropathy remains a potentially catastrophic illness, for which partial but insufficient treatment is currently available.

Scientific Background

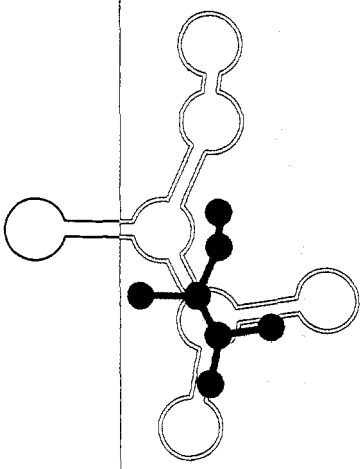
Both DM1 and DM2 are characterized by insufficient insulin effect upon insulin-requiring tissues. As insulin is required for normal metabolism of glucose, fat and protein, diabetes is accompanied by abnormal blood levels of these substances. In the short term, hyperglycemia, or elevated blood glucose, causes the classic symptoms of diabetes: excessive thirst, frequent urination and weight loss. In the long term, hyperglycemia, as well as other effects resulting from insufficient insulin effect, can progressively damage critical anatomic structures resulting in chronic diabetic complications. We are developing sulodexide for the treatment of diabetic nephropathy, a long-term complication of diabetes in which the kidneys are progressively damaged. This progressive damage results in diminished kidney function progressing to ESRD, which ultimately leads to death unless treated by dialysis and/or renal transplant.

The kidney consists of two anatomically and functionally distinct components placed in serial configuration. The first component is the glomerulus, which performs the critical filtering function of the kidney. Blood is passed through delicate microscopic glomerular capillary loops, which, acting as sieves, allow waste chemicals and excess water to pass through into the glomerular filtrate while retaining desirable components, such as blood cells and albumin, within the blood. One of the key components of the glomerular capillary filtering membrane is highly anionic, or negatively charged, glycosaminoglycan molecules that are similar to the chemical components of sulodexide. The glomerular filtrate, which is the precursor of what will eventually be excreted as urine, flows into the next serial component, the tubular interstitial structure. In the tubules, further water is extracted from the filtrate and minerals and other body chemicals are absorbed from or secreted into the filtrate.

In diabetic nephropathy, it is the delicate glomerular loops that first sustain damage as a result of the diabetic state. These harmful effects include:

- The delicate filtering membranes of the glomerular loops thicken and their crucial anionic glycosaminoglycan molecules are either depleted or altered and lose some or all of their negative charge. As the glycosaminoglycan negative charge provides normal filtering selectivity to the glomerular membranes, their loss of negative charge results in the release of protein, usually albumin, from the blood into the filtrate and urine. The releases of abnormal amounts of protein or albumin into the urine are called proteinuria and albuminuria, respectively.
- In addition, hyperglycemia induced overproduction of TGF beta, a regulatory protein, by the kidney induces scar formation in the area surrounding the glomerular capillaries. Over time, the extrinsic pressure of this scar tissue causes collapse of individual glomeruli, loss of functionality and release of albumin into the filtrate and urine.

In normally functioning kidneys, interstitial structures are not exposed to albumin. It is believed that the exposure of the interstitial structures to albumin ultimately leads to a potent inflammatory and scarring response



(mediated in part by TGF beta) in the tubules, as well as in the surrounding interstitial tissues. This scarring results in progressive diminution in kidney function. As might be expected, increasing urinary albumin excretion closely parallels this drop in kidney function. In ESRD, kidney function declines to the point where dialysis or transplantation becomes necessary to sustain life.

KRX-101 belongs to a proposed new class of nephroprotective, or kidney protecting, drugs, known as the glycosaminoglycans. A variety of members of this chemical family have been shown to decrease pathological albumin excretion in diabetic nephropathy in man. Some of the members of this chemical family include the following approved drugs: standard heparin, low molecular weight heparin and danaparoid. However, these agents all require therapy by injection and are all potent anticoagulants, which are blood thinners capable of inducing bleeding. Sulodexide, on the other hand, is given orally and, in this form, has demonstrated little, if any, anticoagulant effects to date.

Pre-Clinical and Clinical Data

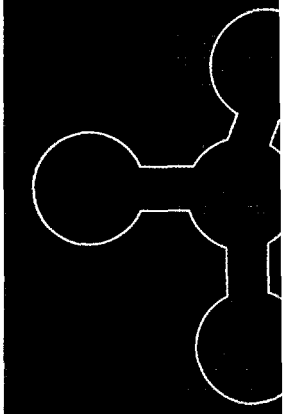
In pre-clinical trials, glycosaminoglycan components similar or identical to those that make up sulodexide have been evaluated using well accepted rodent models of diabetic nephropathy, in both preventive protocols where the drug was given at a time when diabetes was induced and prior to kidney damage, and treatment protocols, where the drug was given after diabetic kidney damage was already present. These glycosaminoglycans diminished the thickening of glomerular capillary filtering membranes, replenished the crucial anionic, or albumin repelling, charge, lowered urinary albumin leakage and decreased kidney expression of the specific scar protein collagen IV, both in the preventive and the treatment protocols, returning these parameters nearly to their normal levels. In addition, data demonstrated that sulodexide suppresses the hyperglycemia-induced, or high glucose-induced, overproduction of TGF beta, one of the most specific inducers of kidney scarring in diabetic and other kidney diseases. Thus, glycosaminoglycans similar or identical to the components of sulodexide in pre-clinical models have prevented or reversed the hallmark "upstream" pathological abnormalities that drive the engine of progressive kidney dysfunction.

There have been more than 20 studies published assessing the safety and efficacy of KRX-101 in humans. KRX-101 has been administered to more than 3,000 patients in clinical trials conducted in Europe for the treatment of certain diabetic and non-diabetic conditions and, to our knowledge, has not demonstrated any significant side effects at the doses tested for those uses.

European researchers, with the support of a grant by Alfa Wassermann S.p.A., or Alpha Wasserman, the licensor of KRX-101, conducted a randomized, double-blind, placebo-controlled, Phase II study of the use of sulodexide to treat diabetic nephropathy in 223 patients in Europe between 1996 and 1999. In this study, also known as the DiNAS study, Type I and Type II diabetics with diabetic nephropathy were treated daily for four months with 50, 100 and 200 milligram gelcaps of KRX-101. These patients showed substantial dose-dependent reduction in proteinuria or pathological urinary albumin excretion rates. In this study, the higher the dose administered daily, the greater the demonstrated decrease in albumin excretion. The DiNAS study was published in the June 2002 issue of the Journal of the American Society of Nephrology.

Development Status

In June 2000, we filed an investigational new drug application, or IND, with the FDA for permission to conduct a clinical trial for the treatment of patients with diabetic nephropathy. In 2001, KRX-101 was granted Fast-Track designation for the treatment of diabetic nephropathy, and, in 2002, we announced that the FDA had agreed, in principle, to permit us to avail ourselves of the accelerated approval process under subpart H of the FDA's regulations governing applications for the approval to market a new drug. Generally, subpart H allows for the use of surrogate endpoints in Phase III trials to support the approval of an NDA with confirmatory studies completed post-approval, and could greatly reduce the development time to market.



In the fourth quarter of 2003, we announced the initiation of a multi-center clinical trial, representing the Phase II portion of our U.S.-based Phase II/III clinical program for the treatment of diabetic nephropathy. This randomized, double-blind, placebo-controlled study will compare two doses (200mg and 400mg daily) of KRX-101 versus placebo. The KRX-101 Phase II/III clinical program is being conducted by the CSG, the world's largest standing renal clinical trial group. In the third quarter of 2004, we completed the target enrollment for the Phase II portion of this clinical program.

In January 2005, we announced that the CSG recommended that we proceed to the Phase III portion of our Phase II/III clinical program of KRX-101 for the treatment of diabetic nephropathy, as planned. This recommendation was based on the completion, by an independent DSMC on January 4, 2005, of a safety evaluation of the first interim analysis from the approximately 150-patient, randomized, double-blind, placebo-controlled Phase II clinical trial of KRX-101, and an efficacy assessment of the same data set conducted by the CSG.

Pursuant to this recommendation, and subject to the successful finalization of our clinical plan with the FDA, we expect to commence our pivotal program, including both Phase III and Phase IV studies for KRX-101, in the first half of 2005. The clinical plan to support an NDA for KRX-101 under Subpart H (accelerated approval) as discussed with the FDA consists of: (i) a Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria; (ii) supportive data from previous clinical studies; and (iii) substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. As part of our commitment to the FDA, we plan to commence the Phase IV trial at approximately the same time as the start of the Phase III trial.

The ultimate clinical timeline, and consequent cost, for further development of KRX-101 will depend, in part, on reaching agreement with the FDA on the specifics of our accelerated approval approach and meeting their conditions for use of such program.

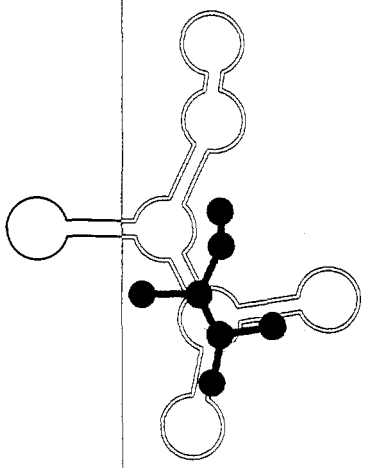
KRX-0401

Overview

KRX-0401 is a novel, first-in-class, oral signal transduction modifier that inhibits the Akt pathway and other important pathways. It has demonstrated preliminary single agent anti-tumor activity and is currently in a Phase II clinical program where it is being studied both as a single agent and in combination with other anti-cancer treatments for multiple forms of cancer.

KRX-0401, or perifosine, is the prototype of a new group of anti-cancer drugs referred to as alkylphosphocholines that block proliferation and induce the apoptosis of cancer cells. This effect is relatively specific for cancer cells compared to normal cells. The mechanism of action for these drugs is not clear. They are known to modulate signaling in a number of pathways known to function abnormally during the development of cancer. One of the pathways inhibited by the alkylphosphocholines is Akt, a pathway associated with tumor survival and growth. Akt appears to be inherently activated in approximately 10-50% of most tumor types and is also believed to be activated by, and thus confer resistance to, most anti-cancer therapies. Based on its prevalence across cancer types and importance in the control of cell survival and cell proliferation, Akt is considered to be one of the most important cancer targets being researched today.

In September 2002, ACCESS Oncology, which we acquired in February 2004, entered into an exclusive commercial license agreement with Zentaris AG, a wholly owned subsidiary of AEterna Zentaris Inc., to acquire a license to a series of U.S. and foreign patents and patent applications relating to the composition of matter and use of KRX-0401 in the treatment of cancer and other conditions. This license agreement covers the United States, Canada and Mexico.



Pre-Clinical and Clinical Data

In vitro, KRX-0401 inhibits the growth of a variety of human tumor cell lines and has substantial activity in vivo against a number of murine tumor models and human xenografts. The drug is synergistic with radiotherapy and additive or synergistic with cytotoxic such as cisplatin, Adriamycin, and cyclophosphamide. In these experiments the combination regimens were superior to chemotherapy alone and were well tolerated.

Five Phase I studies of KRX-0401 have been completed, three in Europe by Zentaris and two in the U.S. by the NCI as part of a CRADA. These trials demonstrated that KRX-0401 can be safely given to humans with an acceptable toxicity profile and no observed myelosuppression, or bone marrow suppression. The dose limiting toxicity in the Phase I studies was gastrointestinal: nausea, vomiting and diarrhea. In addition, some patients experienced fatigue, especially with prolonged administration. In these Phase I studies, there was evidence of single agent activity as evidenced by two durable partial responses (one of which lasted more than six months and the other more than 18 months) out of 10 patients with previously treated, evaluable soft tissue sarcomas, a tumor type relatively unresponsive to chemotherapy. In addition 21 patients were considered by the investigators to have had disease stabilization for two or more months, including patients with sarcomas (2), prostate cancer (3), non-small cell lung cancer (2), breast cancer (2), colon cancer (2), melanoma (2), renal cancer (2), ovarian cancer (1), salivary gland cancer (1), mesothelioma (2) and hepatoma (2). The meaning of disease stabilization in an individual patient in a Phase I study is difficult to assess because many of the patients do not have evaluable disease and disease stabilization, unlike objective responses, may occur spontaneously. Taken together, however, these data provide clinical evidence of the anti-cancer effects of KRX-0401.

The NCI has completed a number Phase II clinical trials studying KRX-0401 as a single agent, conducted and funded by the NCI under a CRADA arrangement with us. To our knowledge, the NCI and its collaborators have presented data from three of their Phase II studies through the date hereof, including from Phase II studies involving sarcoma, head and neck and breast cancers. Findings from these studies led the investigators to conclude that the drug was safe and well-tolerated at the Phase II dose utilized. The studies used dosing schedules in which a large dose, or bolus dose was given on day one or once every 28 days followed by daily doses either continuously or on days two to 21 of a four-week cycle. In these studies, bolus doses ranged from 300 mg to 900 mg followed by daily doses of 100 – 150 mg. These studies confirm the safety profile of the bolus plus daily regimens, which had limited grade 3 and no grade 4 gastrointestinal toxicity, the dose limiting toxicity in most of the Phase I trials. However, studies using a single bolus dose of 600 mg to 900 mg on day one and continuous daily KRX-0401 at a dose of 100 mg per day appeared to be better tolerated than studies that used 150 mg per day on days two to 21 in each four-week cycle. In the sarcoma study, the investigators reported a partial response (greater than 50% decrease in tumor mass) as well as several disease stabilizations. With the responses seen in the Phase I trials, there are now three sarcoma patients with durable partial responses. This has led us to consider exploring additional studies in sarcoma. On the Phase II breast cancer study, the investigators scored three of 15 evaluable patients as having stable disease. One of these patients had measurable tumor regression which failed to reach the level of a partial response by the time the patient elected to withdraw from the study because of gastrointestinal toxicity. The breast cancer trial utilized the more toxic of the regimens employed in these NCI Phase II studies.

Development Status

The NCI, pursuant to the CRADA arrangement referred to above, has completed a Phase II program for KRX-0401 evaluating it as a single-agent in prostate, breast, head and neck and pancreatic cancers, as well as melanoma and sarcomas. In total, nine clinical trials have been conducted across the six tumor types mentioned. To our knowledge, three of the nine clinical trials have been reported. Our expectation is that some of the remainder will be reported at various conferences throughout 2005, including The American Society of Clinical Oncology Annual Meeting.

During the second quarter of 2004, we announced the initiation of the Keryx-sponsored Phase II program for KRX-0401 utilizing KRX-0401 as a single agent and in combination with a number of standard anti-cancer therapies in multiple tumor types.

To date we have initiated several trials under this program. The first is a multi-center study that will evaluate the safety and efficacy of KRX-0401 as a single agent administered weekly to patients with non-small cell lung cancer, or NSCLC, who have progressed despite standard therapy. We have also initiated additional multi-center trials evaluating KRX-0401 in combination with gemcitabine (Gemzar®), paclitaxel (Taxol®) and docetaxel (Taxotere®), all common forms of chemotherapy used to treat multiple tumor types. Recently, we started an "all-comers" Phase II clinical trial evaluating KRX-0401 as a single-agent administered either weekly or daily in a variety of tumor types.

ADDITIONAL PRODUCT CANDIDATES

KRX-0402

KRX-0402 (O6-benzyl guanine or O6-BG) is a small molecule that was specifically designed to block the repair protein, AGT. AGT confers resistance to 06-alkylating agents, such as temozolomide and BCNU, that are commonly used to treat brain cancer, melanoma and non-Hodgkin's lymphoma. Recent research has shown that KRX-0402 can also potentiate the activity of other alkylating agents, such as cisplatinum and carboplatinum, through an as of yet unconfirmed mechanism. These drugs are some of the most widely used chemotherapy drugs and are commonly used to treat breast cancer, non-small cell lung cancer and ovarian cancer. Accordingly, we believe that KRX-0402 may have an important role in making cells more susceptible to the damaging effects of alkylating agents, and that KRX-0402 may have utility in the treatment of multiple forms of cancer. KRX-0402 is usually administered intravenously. To date, approximately 400 patients have received KRX-0402 in multiple clinical studies. Dose limiting toxicity for KRX-0402 in combination with chemotherapy was bone marrow suppression. KRX-0402 alone has no identified dose limiting toxicity. The NCI is currently conducting a randomized Phase III clinical trial of KRX-0402 in patients with previously untreated glioblastoma. Currently, we have plans to conduct additional company-sponsored clinical trials for KRX-0402.

KRX-0403

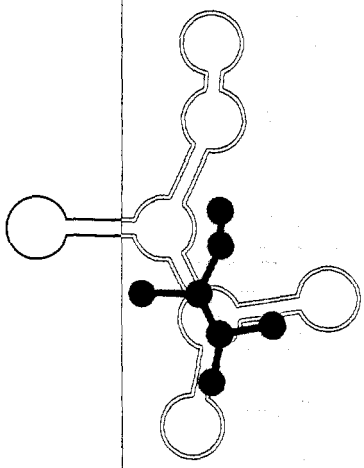
KRX-0403 is a novel spindle poison in the vinca alkaloid class of drugs. We are currently evaluating whether we will continue development of KRX-0403.

KRX-0404

KRX-0404, currently in pre-clinical development, is an alkylphosphocholine, but, in contrast to KRX-0401, it is suitable for intravenous administration.

KRX-0501

KRX-0501, currently in pre-clinical development, is an orally available small molecule in pre-clinical development with the potential to treat neurological disorders via its unique ability to enhance nerve growth factor, a naturally occurring protein which is essential in the developments and survival of certain sympathetic and sensory neurons in both the central and peripheral nervous systems.



INTELLECTUAL PROPERTY AND PATENTS

General

Patents and other proprietary rights are very important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. It is our intention to seek and maintain patent and trade secret protection for our drug candidates and our proprietary technologies. As part of our business strategy, our policy is to actively file patent applications in the United States and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and compositions and improvements in each of these. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. We have a number of patents and patent applications related to our compounds and other technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that the pending patent applications will issue as patents.

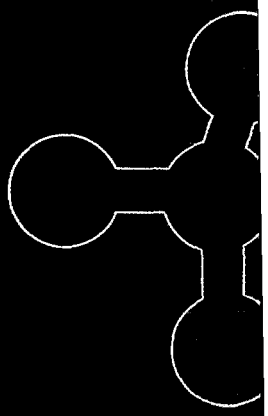
Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent.

If patents are issued to others containing preclusive or conflicting claims and these claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. Our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would create substantial costs. An adverse outcome in litigation could subject us to significant liabilities to third parties and require us to seek licenses of the disputed rights from third parties or to cease using the technology if such licenses are unavailable.

KRX-101

Pursuant to our license for KRX-101, we have the rights to ten patent families, including nine families of issued U.S. patents and foreign counterparts, and one family of a pending U.S. patent application and foreign counterparts. Of the ten patent families, five patent families cover processes for the manufacture of heparin and glycosaminoglycans, and five patent families cover the use of KRX-101 (sulodexide) and glycosaminoglycans for the treatment of diabetic nephropathy, neuropathy and retinopathy. These patent applications are being maintained throughout the territories in which they were filed.

In addition to the licensed patents, we have filed in the name of Keryx, six patent families of U.S. patent applications and foreign counterparts directed to the use of KRX-101 and glycosaminoglycans for the treatment of



various indications such as HIV-related nephropathy, inflammatory bowel disease, bladder disease, kidney disease and preeclampsia.

The licensed patents will expire at various times between 2012 and 2022. Currently, the use of KRX-101 to treat diabetic nephropathy is covered by an issued U.S. patent which expires in 2014 and a pending U.S. patent application which, if allowed, will expire in 2022. Based on the provisions of the Patent Term Extension Act, we currently believe that we would qualify for patent term extension of at least three years, thereby extending our patent exclusivity, for the issued U.S. patent to at least 2017 and for the pending U.S. patent application, if allowed, to 2025. We, therefore, believe that we will have sufficient time to commercially utilize the inventions directed to the treatment of diabetic nephropathy.

Clinical-Stage Oncology Compounds, including KRX-0401

Pursuant to our acquisition of ACCESS Oncology in February 2004, we have the exclusive commercial rights to a series of patents and patent applications in the United States, Canada and Mexico related to KRX-0401. These patents and patent applications cover composition of matter and methods of treatment. In addition, as a result of the acquisition, we have obtained the exclusive commercial rights to a series of patents and patent applications related to KRX-0402 and KRX-0403.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

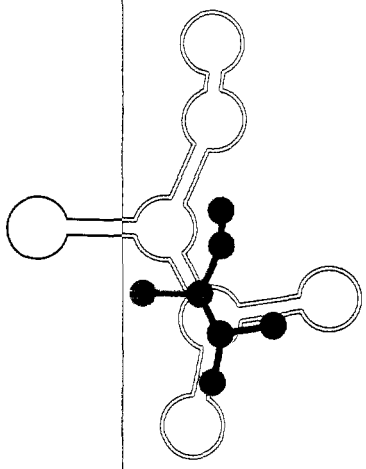
In addition to patent protection, we may utilize orphan drug regulations to provide market exclusivity for certain of our drug candidates. The orphan drug regulations of the FDA provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the United States, or, diseases that affect more than 200,000 individuals in the United States but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. We believe that certain of the indications for our drug candidates will be eligible for orphan drug designation; however, we cannot assure you that our drugs will obtain such orphan drug designation or will be the first to reach the market and provide us with such market exclusivity protection.

LICENSING AGREEMENTS AND COLLABORATIONS

We have formed strategic alliances with a number of companies for the manufacture and commercialization of our products. Our current key strategic alliances are discussed below.

Alfa Wassermann S.p.A.

Under a license agreement with Alfa Wassermann, we have the exclusive rights to KRX-101 for diabetic nephropathy, neuropathy and retinopathy in the United States, Canada, Japan, Australia, New Zealand, South Africa and Israel. The license entitles Alfa Wassermann to annual license fees and certain milestone payments.



Under the license, we must use our reasonable best efforts to commercialize and market KRX-101. Alfa Wassermann must pay us a royalty, to the extent that it or its sub-licensees receive revenues from products that incorporate information or know-how that we develop. The license terminates upon the later of the expiration of all underlying patent rights or 10 years from our first commercial sale of KRX-101.

Collaborative Study Group

In August 2003, we announced that the CSG will be conducting our U.S.-based Phase II/III clinical program for KRX-101 for the treatment of diabetic nephropathy. The CSG receives a monthly fee and reimbursement of expenses from us as compensation for its work in connection with this clinical program. The CSG also has the right to publish data arising from the clinical program. The agreement remains in force as long as the clinical program is ongoing. We may terminate the agreement at any time upon 30 days written notice, and the CSG has the right to terminate the agreement upon our material breach of the agreement, unless cured within 30 days.

Opocrin, S.p.A.

Pursuant to a license with Opocrin, S.p.A., a private drug manufacturer, we have a non-exclusive worldwide license to the manufacturing process of KRX-101 for a period of twelve years from the date of the first commercial sale of the product. Notwithstanding this right, Opocrin shall have the right to terminate the agreement on 60 days notice in the event that we have not submitted an NDA to the FDA by December 31, 2007.

AEterna Zentaris Inc.

In September 2002, we signed a commercial license agreement with Zentaris AG, a wholly owned subsidiary of AEterna Zentaris Inc., relating to the development of KRX-0401 covering composition of matter and methods of treatment. This agreement grants us the exclusive rights to KRX-0401 in the United States, Canada and Mexico. Zentaris is entitled to certain royalty payments, as well as additional compensation upon successful achievement of certain milestones. The license terminates upon the later of the expiration of all underlying patent rights or 10 years from the first commercial sale of KRX-0401 in any of the covered territories. We also have the right to extend the agreement for an additional five years beyond the expiration of all underlying patents.

Paligent, Inc.

In October 2000, we entered into a worldwide, exclusive commercial sub-license agreement with Procept, Inc., or Procept, a wholly owned subsidiary of Paligent, Inc., relating to the development and marketing of KRX-0402. Under the license agreement, we have assumed responsibility for the development and marketing of KRX-0402. Procept is entitled to certain milestone payments, as well as royalty payments on net sales of KRX-0402. The license terminates upon the expiration of all underlying patent rights.

Prescient NeuroPharma Inc.

In December 2001, we entered into an exclusive commercial sub-license agreement with Prescient NeuroPharma Inc., or Prescient, relating to the development and marketing of KRX-0403. The KRX-0403 license agreement provides for worldwide sublicense rights, with the exception of the Far East. Prescient is entitled to certain milestone payments under the terms of the agreement. In addition, the agreement provides that we will make certain milestone and royalty payments on net sales of KRX-0403. The agreement with Prescient terminates on the later of the date the last patent expires in the patent portfolio or the end of the orphan drug designation period by the FDA, if applicable.

COMPETITION

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceuticals companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition

for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier.

SUPPLY AND MANUFACTURING

We currently have no manufacturing capabilities. In 2003, we entered into a contract manufacturing agreement with a U.S.-based manufacturer for the supply of KRX-101 drug product. We believe that this contract manufacturer will be adequate to satisfy our current clinical and initial commercial supply needs. However, we will need to confirm a reproducible manufacturing process that will ensure consistent quality of KRX-101 across multiple batches and sources. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, the creation of a reproducible process will be required for the successful commercialization of KRX-101. We cannot be certain that we will be successful in this endeavor.

The creation of a reproducible process is also critical in successfully sourcing KRX-101 from multiple suppliers either to create back-up manufacturing capabilities and/or to meet market demand. We have discussed the issue of multi-sourcing with the FDA and they have indicated that they would likely permit such multi-sourcing provided the manufacturing process used by multiple manufacturers remains uniform.

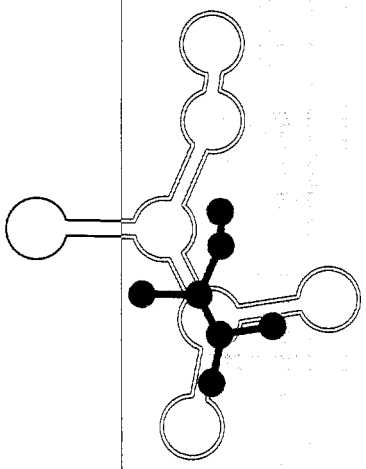
The materials used to manufacture KRX-101, like all heparin-like compounds, are derived from porcine mucosa. Long-term supplies for KRX-101 could be affected by limitations in the supply of porcine mucosa and the demand for other heparin products. Diseases affecting the world supply of pigs could have an actual or perceived negative impact on our ability to source, make or sell KRX-101. All of these factors could have an adverse affect on the commercial success of KRX-101.

In addition, we have established contract manufacturing relationships for the supply of KRX-0401 and KRX-0402.

At the time of commercial sale, to the extent possible and commercially practicable, we plan to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited numbers of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for conducting clinical trials or for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect our contractor's ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic inspections by the FDA, the Drug Enforcement Agency and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations.



Our contractors in Europe face similar challenges from the numerous European Union and member state regulatory agencies. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations.

If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATION

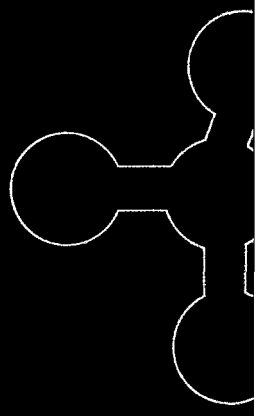
Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our drug candidates, as well as our ongoing research and development activities. None of our drug candidates have been approved for sale in any market in which we have marketing rights. Before marketing in the United States, any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, or the Federal Food, Drug, and Cosmetic Act. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the NDA. To receive fast track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition;
- that the drug is intended to treat a serious aspect of the condition; and
- that the drug has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug development programs ordinarily are eligible for priority review and also may be permitted to submit portions of an NDA to the FDA for review before the complete application is submitted. In 2001, KRX-101 received fast track designation.



Sponsors of drugs designated as fast track also may seek approval under the FDA's accelerated approval regulations under subpart H. Pursuant to subpart H, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Post-marketing studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence.

In November of 2002, we announced that the FDA agreed in principal that the NDA for KRX-101 may be filed under subpart H. Final approval will be based on a determination by the FDA of the safety and efficacy of KRX-101 based on a surrogate endpoint. We have submitted a subpart H clinical development plan to the FDA for the clinical development of KRX-101 for diabetic nephropathy. A final agreement on the specifics of our clinical program for that development plan is pending finalization with the FDA, but we cannot give any assurance that an acceptable final agreement on the specifics of such clinical program will ever be reached with the FDA. Additionally, the subpart H process is complex and requires careful execution. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval.

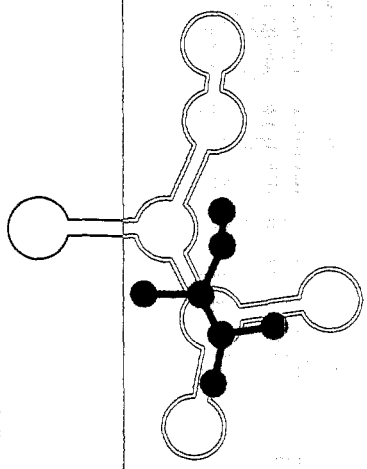
Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

- Phase I: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.
- Phase II: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.
- Phase III: Studies establish safety and efficacy in an expanded patient population.
- Phase IV: The FDA may require a Phase IV to conduct post-marketing studies for purposes of gathering additional evidence of safety and efficacy.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;
- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;
- insufficient supply of the drug candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the drug candidates.



In addition, the FDA may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

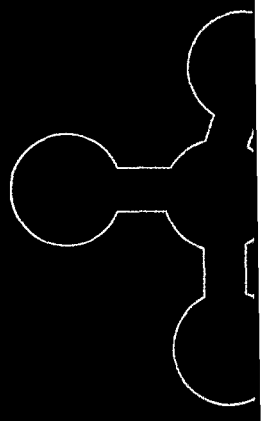
Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP. Manufacturers must expend time, money and effort to ensure compliance with cGMP, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA will not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will be limited to those specified in an FDA approval, and the advertising of our products will be subject to comprehensive regulation by the FDA. Claims exceeding those that are approved will constitute a violation of the Federal Food, Drug, and Cosmetic Act. Violations of the Federal Food, Drug, and Cosmetic Act or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Should we wish to market our products outside the United States, we must receive marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the European Union, registration procedures are available to companies wishing to market a product in more than one European Union member state. If the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, the regulatory authority will grant a marketing authorization. This foreign regulatory approval process involves all of the risks associated with FDA approval discussed above.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manu-



facture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

RESEARCH AND DEVELOPMENT

Company-sponsored research and development expenses (excluding non-cash compensation and acquired in-process research and development expenses) totaled $9,523,000 in 2002, $5,996,000 in 2003, and $9,805,000 in 2004, respectively. "Other research and development expenses" consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, testing, and enhancement of our product candidates, as well as expenses related to in-licensing or acquisition of new product candidates.

EMPLOYEES

We currently have 27 full- and part-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

RISK FACTORS

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks Related to Our Business

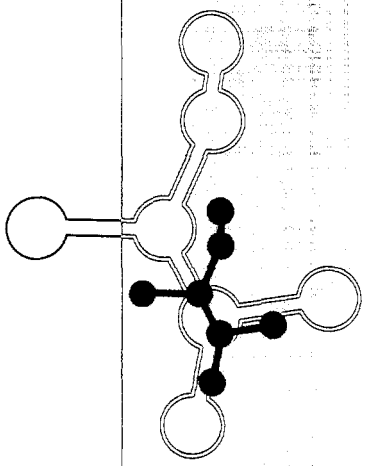
We have a limited operating history and have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2004, we had an accumulated deficit of approximately $87.6 million. As we expand our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates or technologies.

We have not yet commercialized any products or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidates and successfully commercialize our drug candidates and technologies.

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective basis.



Additionally, we have submitted a subpart H clinical development plan to the FDA for the clinical development of KRX-101 for diabetic nephropathy. A final agreement on the specifics of our clinical program for that development plan is pending finalization with the FDA, but we cannot give any assurance that an acceptable final agreement on the specifics of such clinical program will ever be reached with the FDA. Additionally, the FDA has previously commented that, based on the novelty of the approach that we have discussed with them, they may want to refer our proposed approach to the Cardio-Renal Advisory Committee.

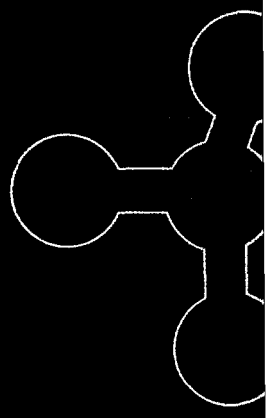
Moreover, even if we are able to reach final agreement with the FDA regarding the specifics of an accelerated approval approach, no assurance can be given that we will be able to meet the requirements set forth in such agreement. The subpart H process is complex and requires careful execution. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. The clinical timeline, scope and consequent cost for the development of KRX-101 will depend, in part, on the final outcome of our discussions with the FDA. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

If our drug candidates do not receive the necessary regulatory approvals, we will be unable to commercialize our drug candidates.

We have not received, and may never receive, regulatory approval for commercial sale for any of our drug candidates. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. It may take us many years to complete the testing of our drug candidates and failure can occur at any stage of this process. Negative or inconclusive results or medical events during a clinical trial could cause us to delay or terminate our development efforts.

Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies. Drug candidates in later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. Specifically, we recently received the recommendation to proceed, as planned, into our pivotal Phase III and Phase IV program for KRX-101 from the Collaborative Study Group. This recommendation was made pursuant to a safety and efficacy assessment of a first interim analysis of data from our ongoing Phase II study for KRX-101. There can be no assurance that the full data from the Phase II study will track the data from the first interim analysis of the Phase II study upon which the recommendation to move forward was made. Moreover, this recommendation to move into our pivotal program, as well as any further results from our Phase II trial, if they are positive, may not be indicative of results from future clinical trials and the risk remains that the pivotal program for KRX-101 may generate efficacy data that will be insufficient for the approval of the drug, or may raise safety concerns that may prevent approval of the drug.

Clinical trials also have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. If we experience delays in the testing or approval process or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the United States and abroad and, accordingly, may encounter unforeseen problems and delays in the approval process.



Because we license our proprietary technologies, termination of these agreements would prevent us from developing our drug candidates.

We do not own any of our drug candidates. We have licensed the patent rights to these drugs candidates from others. These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates.

If we do not establish or maintain drug development and marketing arrangements with third parties, we may be unable to commercialize our technologies into products.

We are an emerging company and do not possess all of the capabilities to fully commercialize our product candidates on our own. From time to time, we may need to contract with third parties to:

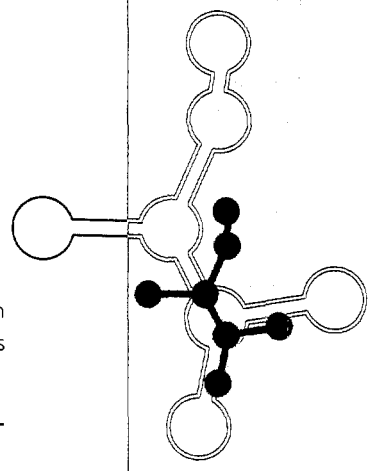
- assist us in developing, testing and obtaining regulatory approval for and commercializing some of our compounds and technologies; and
- market and distribute our drug candidates.

We can provide no assurance that we will be able to successfully enter into agreements with such partners on terms that are acceptable to us. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our technologies independently, which could result in delays. Further, such failure could result in the termination of license rights to one or more of our technologies. Moreover, if these development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of products based on our technologies. Accordingly, to the extent that we rely on third parties to research, develop or commercialize products based on our technologies, we are unable to control whether such products will be scientifically or commercially successful.

Even if we obtain FDA approval to market our product candidates, if our products fail to achieve market acceptance, we will never record meaningful revenues.

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our product candidates will depend on a number of factors, including:

- perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidates;
- the rates of adoption of our products by medical practitioners and the target populations for our products;
- the potential advantages that our product candidates offer over existing treatment methods;
- the cost-effectiveness of our product candidates relative to competing products;
- the availability of government or third-party payor reimbursement for our product candidates;
- the side effects or unfavorable publicity concerning our products or similar products; and
- the effectiveness of our sales, marketing and distribution efforts.



Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues in the long-term, the failure of our drugs to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

We rely on third parties to manufacture our products. If these third parties do not successfully manufacture our products, our business will be harmed.

We have no experience in manufacturing products for clinical or commercial purposes and do not have any manufacturing facilities. We intend to continue to use third parties to manufacture our products for use in clinical trials and for future sales. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms, if at all.

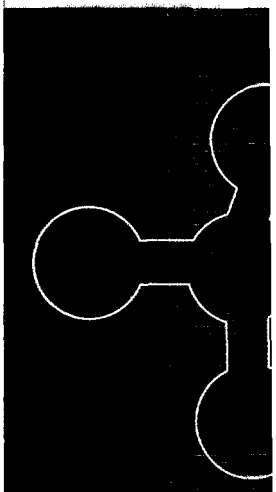
Contract manufacturers often encounter difficulties in scaling up production, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and foreign regulations, production costs and development of advanced manufacturing techniques and process controls. Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidates. In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with, among other things, current good manufacturing practices, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. Switching or engaging multiple manufacturers may be difficult because the number of potential manufacturers is limited and, particularly in the case of KRX-101, the process by which multiple manufacturers make the drug substance must be identical at each manufacturing facility. It may be difficult for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. Moreover, if we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to deliver the required quantities of our drug candidates on a timely basis and at commercially reasonable prices, we will not be able to commercialize our products as planned.

We have entered into a contract manufacturing relationship with a U.S.-based contract manufacturer for KRX-101 which we believe will be adequate to satisfy our current clinical and initial commercial supply needs; however, as we transition the manufacturing of KRX-101 to our U.S.-based contract manufacturer, we will need to create a reproducible manufacturing process that will ensure consistent manufacture of KRX-101 across multiple batches and sources. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, the creation of a reproducible process will be required for the successful commercialization of KRX-101. There can be no assurance that we will be successful in this endeavor.

If we are not able to obtain the raw materials required for the manufacture of our lead product candidate, KRX-101, our ability to develop and market this product candidate will be substantially harmed.

Source materials for KRX-101, our lead product candidate, are derived from porcine mucosa. Long-term supplies for KRX-101 could be affected by limitations in the supply of porcine mucosa and the demand for other heparin products, over which we will have no control. Additionally, diseases affecting the world supply of pigs could have an actual or perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell KRX-101. Such negative impact could materially affect the commercial success of KRX-101.



If our competitors develop and market products that are less expensive, more effective or safer than our product candidates, our commercial opportunities may be reduced or eliminated.

The pharmaceutical industry is highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our technologies or our drug candidates obsolete or noncompetitive. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

Our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug candidates. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors.

If we lose our key personnel or are unable to attract and retain additional personnel, our operations could be disrupted and our business could be harmed.

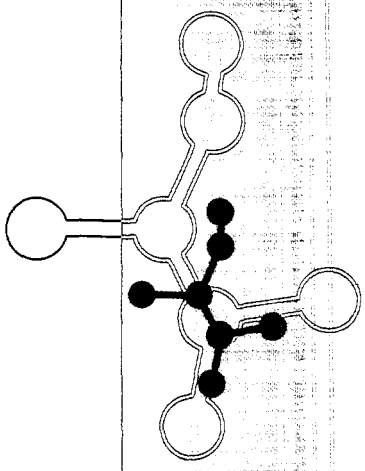
We currently have 27 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. In addition, while we have an employment agreement with Mr. Weiss, this agreement would not prevent him from terminating his employment with us.

Any acquisitions we make may dilute your equity or require a significant amount of our available cash and may not be scientifically or commercially successful.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes stock or other securities, your equity in us may be significantly diluted. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- inability to retain the management, key personnel and other employees of the acquired business;
- inability to maintain the acquired company's relationship with key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired business prior to acquisition;
- diversion of management attention; and
- potential impairment of substantial goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.



We face product liability risks and may not be able to obtain adequate insurance.

The use of our drug candidates in clinical trials, and the sale of any approved products, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates or limit commercialization of any approved products.

We believe that we have obtained sufficient product liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for a product;
- injury to our reputation;
- inability to continue to develop a drug candidate;
- withdrawal of clinical trial volunteers; and
- loss of revenues.

Consequently, a product liability claim or product recall may result in losses that could be material.

In connection with providing our clinical trial management and site recruitment services, we may be exposed to liability that could have a material adverse effect on our financial condition and results of operations.

OCOG, a subsidiary we acquired through our acquisition of ACCESS Oncology, provides clinical trial management and site recruitment services to us as well as other biotechnology and pharmaceutical companies. In conducting the activities of OCOG, any failure on our part to comply with applicable governmental regulations or contractual obligations could expose us to liability to our clients and could have a material adverse effect on us. We also could be held liable for errors or omissions in connection with the services we perform. In addition, the wrongful or erroneous delivery of health care information or services may expose us to liability. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any such claims.

Risks Related to Our Financial Condition

Our current cash, cash equivalents and short-term securities may not be adequate to support our operations for the next 24 to 30 months as we have estimated.

We believe that our $49.9 million in cash, cash equivalents, interest receivable and short-term securities as of December 31, 2004, will be sufficient to enable us to meet our planned operating needs and capital expenditures for approximately the next 24 to 30 months. Our forecast of the period of time through which our cash, cash equivalents and short-term securities will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the timing of expenses associated with manufacturing and product development of the proprietary drug candidates within our portfolio and those that may be in-licensed, partnered or acquired;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;

- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the amount of any funds expended to repurchase our common stock.

If we are unable to obtain additional funds on terms favorable to us, or at all, our business would be harmed.

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current plans, we believe our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital requirements for approximately the next 24 to 30 months; however, the actual amount of funds that we will need prior to or after that date will be determined by many factors, some of which are beyond our control. As a result, we may need funds sooner or in different amounts than we currently anticipate, depending upon:

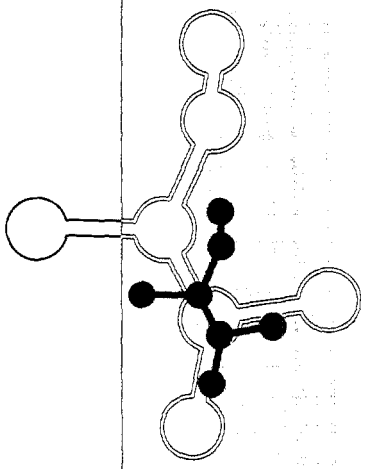
- the progress of our development activities;
- the progress of our research activities;
- the number and scope of our development programs;
- our ability to establish and maintain current and new licensing or acquisition arrangements;
- our ability to achieve our milestones under our licensing arrangements;
- the costs involved in enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our technology. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we raise additional funds through the sale or license of our technology, we may be unable to do so on terms favorable to us.

Our prior restructurings may result in additional Israeli-related liabilities.

In September 2001, one of our Israeli subsidiaries received the status of an "Approved Enterprise," a status which grants certain tax benefits in Israel in accordance with the "Law for the Encouragement of Capital Investments, 1959." Through December 31, 2003, our Israeli subsidiary, which ceased operations in 2003, has received tax benefits in the form of exemptions of approximately $744,000 as a result of our subsidiary's status as an "Approved Enterprise." As part of the restructuring implemented during 2003, we closed down our Jerusalem laboratory facility. In October 2003, the subsidiary received a letter from the Israeli Ministry of Industry and Trade that its Approved Enterprise status was cancelled as of July 2003 and that past benefits would not need to be repaid. The Israeli tax authorities have yet to confirm this position; however, we believe that, based on the letter received from the Ministry of Industry and Trade, it is unlikely that past benefits will need to be repaid, and therefore, we have not recorded any charge with respect to this potential liability. There can be no assurances that the Israeli tax authorities will confirm this position. As a result, we may be liable to repay some or all of the tax benefits received to date, which could adversely affect our cash flow and results of operations.

In July 2003, our Israeli subsidiaries vacated their Jerusalem facility and relocated to smaller facilities. The landlord of the Jerusalem facility has alleged that we were immediately liable to pay the landlord a sum in excess of $1.1 million as a result of the alleged breach of the lease agreement for the Jerusalem facility. The amount



demanded by the landlord includes rent for the entire remaining term of the lease (through 2005), as well as property taxes and other costs. In August 2003, the landlord claimed a bank guarantee, in the amount of $222,000, which was previously provided as security in connection with the lease agreement, making the net amount potentially due to the landlord $776,000. To date, no litigation has been initiated, and, to our knowledge, the landlord has succeeded in leasing most, if not all, of the space to one or more new tenants.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents and technologies against third-party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

Moreover, we rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to some of our drug candidates with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.

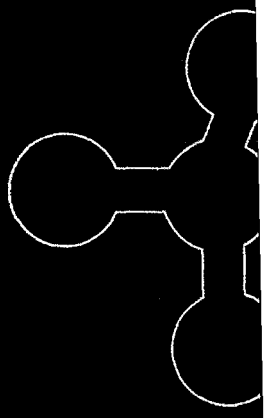
Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money defending such claims and adversely affect our ability to develop and commercialize our products.

Third parties may assert that we are using their proprietary technology without authorization. In addition, third parties may have or obtain patents in the future and claim that our technologies infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected technologies could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Risks Related to Our Common Stock

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

As of December 31, 2004, our executive officers, directors and principal stockholders (including their affiliates) beneficially owned, in the aggregate, approximately 24.3% of our outstanding common stock, including, for this purpose, currently exercisable options and warrants held by our executive officers, directors and principal stockholders. As a result, these persons, acting together, may have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and



any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of our common stock.

Future sales of our common stock could depress the market for our common stock.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future. On September 29, 2004, we filed with the SEC a shelf registration statement on Form S-3, which the SEC declared effective on October 13, 2004, providing for the offering of up to five million shares of our common stock. Future sales pursuant to this registration statement could depress the market for our common stock.

Additionally, our executive officers, directors, and principal stockholders beneficially owned, in the aggregate, approximately 24.3% of our common stock as of December 31, 2004, including currently exercisable warrants and options held by them. If some or all of them should decide to sell a substantial number of their holdings, it could have a material adverse effect on the market for our common stock.

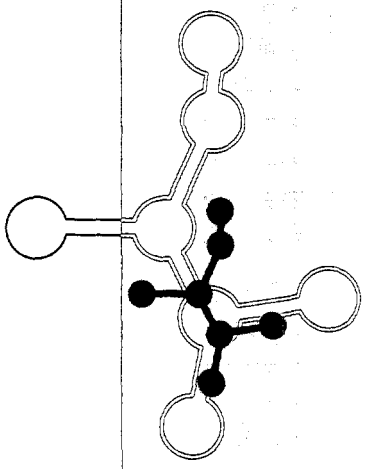
Our stock price can be volatile, which increases the risk of litigation, and may result in a significant decline in the value of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- developments concerning our drug candidates;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in quarterly operating results;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies; and
- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business.

The concentration of stock ownership by our executive officers, directors and principle stockholders and certain anti—takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.



As of December 31, 2004, our executive officers, directors and principal stockholders (including their affiliates) beneficially owned, in the aggregate, approximately 24.3% of our outstanding common stock, including, for this purpose, currently exercisable options and warrants held by our executive officers, directors and principal stockholders. In addition, provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock with rights senior to those of the common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

ITEM 2. PROPERTIES.

Our corporate and executive office is located in New York, New York. Our New York facility consists of approximately 11,700 square feet of leased space at 750 Lexington Avenue, New York, New York 10022. In addition, we are currently evaluating various possibilities of leasing approximately 2,000 square feet of space in the San Francisco, California area, to accommodate our oncology group, which is currently based in San Francisco. We recorded a $50,000 facility expense, in the year ended December 31, 2004, for the use of the personal facility of our President for several of our employees located in San Francisco. We anticipate that these facilities will be sufficient for our needs during the next several years.

ITEM 3. LEGAL PROCEEDINGS.

We, and our subsidiaries, are not a party to, and our property is not the subject of, any material pending legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

We did not submit any matters to a vote of our security holders, through the solicitation of proxies or otherwise, during the fourth quarter of 2004.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is listed on the Nasdaq National Market and trades under the symbol "KERX." Trading of our common stock commenced on July 28, 2000, following the completion of our initial public offering.

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

Fiscal Year Ended December 31, 2004	High	Low
Fourth Quarter	$ 13.80	$ 9.65
Third Quarter	$ 12.90	$ 7.13
Second Quarter	$ 19.07	$ 10.57
First Quarter	$ 15.42	$ 4.59

Fiscal Year Ended December 31, 2003	High	Low
Fourth Quarter	$ 5.46	$ 3.23
Third Quarter	$ 3.85	$ 2.15
Second Quarter	$ 2.68	$ 1.10
First Quarter	$ 1.60	$ 1.28

Holders

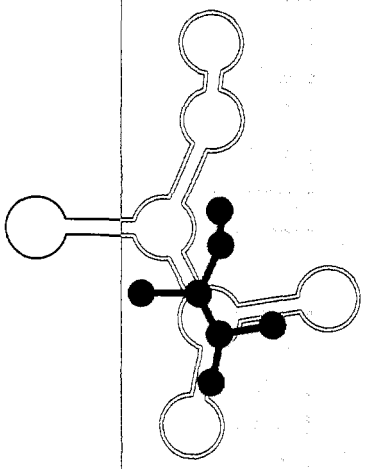
The number of record holders of our common stock as of March 4, 2005 was 64.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2004, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1999 Stock Option Plan, as amended, the 2000 Stock Option Plan, as amended, the Non-Plan, the 2002 CEO Incentive Stock Option Plan, the 2004 President Incentive Plan and the 2004 Long-Term Incentive Plan.



Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	4,476,964	$ 2.86	4,232,822
Equity compensation plans not approved by security holders	3,716,210	$ 2.64	22,500
Total	8,193,174	$ 2.76	4,255,322

For information about all of our stock option plans, see Note 7 to our Consolidated Financial Statements.

ITEM 6. SELECTED FINANCIAL DATA.

The following Statement of Operations Data for the years ended December 31, 2004, 2003, 2002, 2001 and 2000, and Balance Sheet Data as of December 31, 2004, 2003, 2002, 2001 and 2000, as set forth below are derived from our audited consolidated financial statements. This financial data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data."

	Years Ended December 31,				
(in thousands, except per share data)	**2004**	**2003**	**2002**	**2001**	**2000**
Statement of Operations Data:					
Service revenue	**$ 809**	$ —	$ —	$ —	$ —
Operating expenses:					
Cost of services	**835**	—	—	—	—
Research and development:					
Non-cash compensation	**413**	(486)	(1,382)	(17)	3,186
Non-cash acquired in-process research and development	**18,800**	—	—	—	—
Other research and development	**9,805**	5,996	9,523	7,416	3,500
Total research and development	**29,018**	5,510	8,141	7,399	6,686
General and administrative:					
Non-cash compensation	**1,087**	188	(4)	139	2,668
Other general and administrative	**3,581**	3,684	4,108	4,302	3,232
Total general and administrative	**4,668**	3,872	4,104	4,441	5,900
Total operating expenses	**34,521**	9,382	12,245	11,840	12,586
Operating loss	**(33,712)**	(9,382)	(12,245)	(11,840)	(12,586)
Other income (expense):					
Interest and other income, net	**770**	247	513	2,231	1,317
Income taxes	**(1)**	27	(51)	(197)	(220)
Net loss	**$ (32,943)**	$ (9,108)	$ (11,783)	$ (9,806)	$ (11,489)
Net loss per common share					
Basic and diluted	**$ (1.10)**	$ (0.43)	$ (0.59)	$ (0.50)	$ (0.89)

(in thousands)	As of December 31, 2004	2003	2002	2001	2000
Balance Sheet Data:					
Cash, cash equivalents, interest receivable and investment securities	**$ 49,878**	$ 31,414	$ 24,131	$ 37,856	$ 48,900
Working capital	**46,538**	30,982	22,350	35,235	37,908
Total assets	**50,862**	32,223	29,103	43,067	50,264
Long-term obligations	**92**	—	256	766	304
Contingent equity rights	**4,004**	—	—	—	—
Total stockholders' equity	**42,804**	31,226	26,330	39,215	48,867

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Business – Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report

You should read the following discussion and analysis in conjunction with "Item 6. Selected Financial Data" and "Item 8. Financial Statements and Supplementary Data" appearing elsewhere in this report.

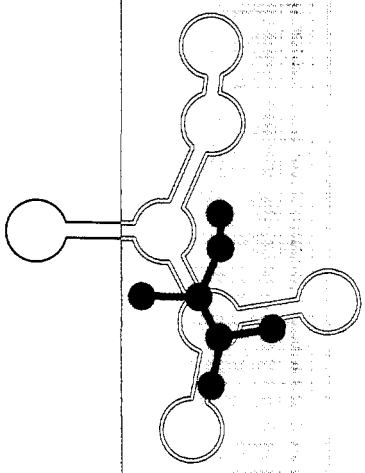
OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. We have two product candidates in the later stages of clinical development: sulodexide, or KRX-101, for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes, and perifosine, or KRX-0401, for the treatment of multiple forms of cancer.

We were incorporated in Delaware in October 1998. We commenced operations in November 1999, following our acquisition of substantially all of the assets and certain of the liabilities of Partec Ltd., our predecessor company that began operations in January 1997. Since commencing operations, our activities have been primarily devoted to developing our technologies and drug candidates, acquiring clinical-stage compounds, raising capital, purchasing assets for our facilities, and recruiting personnel. We are a development stage company and have no product sales to date. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, and from our initial public offering.

We are a development stage company and have devoted substantially all of our efforts to the discovery, in-licensing and development of drug candidates. We have incurred negative cash flow from operations each year since our inception. We anticipate incurring negative cash flows from operating activities for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and potential in-licensing and acquisition opportunities.

Our revenues consist of clinical trial management and site recruitment services. Revenues from providing these services are recognized as the services are provided. Deferred revenue is incurred when we receive a deposit or prepayment for services to be performed at a later date.



Our cost of services consist of all costs specifically associated with client programs such as salaries, benefits paid to personnel, payments to third-party vendors and systems and other support facilities associated with delivering services to our clients. Cost of services are recognized as services are performed.

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, testing, and enhancement of our product candidates, as well as expenses related to in-licensing and acquisition of new product candidates. We expense our research and development costs as they are incurred.

Our general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, general legal activities and facilities related expenses. We anticipate that general and administrative expenses will increase for the foreseeable future as we expand our operating activities and as a result of increased costs associated with being a publicly-traded company.

Our results of operations include non-cash compensation expense as a result of the grants of stock, stock options and warrants. Compensation expense for fixed award options and warrants granted to employees and directors represents the intrinsic value (the difference between the stock price of the common stock and the exercise price of the options or warrants) of the options and warrants at the date of grant. For variable awards, we consider the difference between the stock price at reporting date and the exercise price, in the case where a measurement date has not been reached. The compensation cost is recorded over the respective vesting periods of the individual stock options and warrants. The expense is included in the respective categories of expense in the statement of operations. We expect to incur significant non-cash compensation expense in the future; however, because some of the options and warrants issued to employees, consultants and other third-parties either do not vest immediately or vest upon the achievement of certain milestones, the total expense is uncertain.

Our ongoing clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our product candidates in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

RESULTS OF OPERATIONS

Years Ended December 31, 2004 and 2003

Revenue. Service revenue for the year ended December 31, 2004, was $809,000 as compared to no revenue for the year ended December 31, 2003. Service revenue for the year ended December 31, 2004 was generated by OCOG, a subsidiary acquired through our acquisition of ACCESS Oncology in the first quarter of 2004. We do not expect our service revenue to have a material impact on our financial results during the next year.

Cost of Services Expense. Cost of services expense for the year ended December 31, 2004 was $835,000 as compared to no cost of services expense for the year ended December 31, 2003. Cost of services expense for the year ended December 31, 2004 was generated by OCOG, a subsidiary acquired through our acquisition of ACCESS Oncology in the first quarter of 2004. We do not expect our cost of services expenses to have a material impact on our financial results during the next year.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants and warrant issuances was $413,000 for the year ended December 31, 2004, as com-

pared to negative $486,000 for the year ended December 31, 2003. This increase in non-cash compensation expense was primarily due to the issuance of options to consultants accounted for using the fair value method as well as due to the adjustment to fair market value of previously-issued options to consultants.

Non-Cash Acquired In-Process Research and Development Expense. As required by Financial Accounting Standards Board Interpretation No. 4, "Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method," or FIN 4, the Company recorded a charge of $18,800,000 in the year ended December 31, 2004 for the estimate of the portion of the purchase price of ACCESS Oncology allocated to acquired in-process research and development. A project-by-project valuation was performed with the assistance of independent valuation specialists to determine the fair value of research and development projects of ACCESS Oncology which were in-process, but not yet completed.

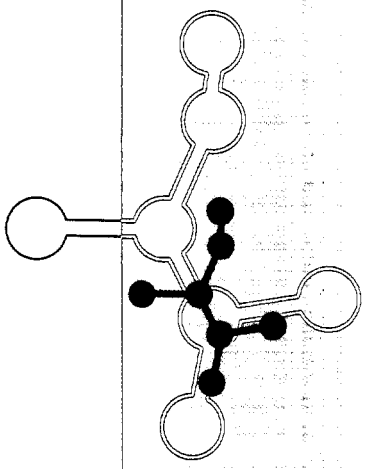
Other Research and Development Expenses. Other research and development expenses increased by $3,809,000 to $9,805,000 for the year ended December 31, 2004, as compared to expenses of $5,996,000 for the year ended December 31, 2003. The increase in other research and development expenses was due primarily to a $3,990,000 increase in expenses related to KRX-101, which includes one-half, or $500,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a milestone, a $2,853,000 increase in expenses related to our oncology drug portfolio, and an increase in our licensing costs of $550,000 for the in-licensing of a pre-clinical compound. This increase was partially offset by the absence of a $2,358,000 non-cash impairment charge associated with our 2003 restructuring that was taken during the comparative period last year, as well as the absence of $964,000 in expenses related to early-stage research and development which ceased in 2003.

We expect our other research and development costs to increase over the next year as a result of our U.S.-based clinical program for KRX-101 and the clinical program for KRX-0401, including the planned commencement of additional single agent and combination trials, as well as possible development programs for the other drug candidates within our portfolio.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense related to stock option grants was $1,087,000 for the year ended December 31, 2004, as compared to expenses of $188,000 for the year ended December 31, 2003. This increase in non-cash compensation expense was primarily due to the issuance of previously granted options to purchase shares of our common stock to two non-employee directors at an exercise price less than market price at issue date (but equal to market price at grant date) and due to the issuance of options to consultants accounted for using the fair value method, as well as due to the adjustment to fair market value of previously-issued options to consultants.

Other General and Administrative Expenses. Other general and administrative expenses decreased by $103,000 to $3,581,000 for the year ended December 31, 2004, as compared to expenses of $3,684,000 for the year ended December 31, 2003. The decrease in general and administrative expenses was due primarily to the absence of a $124,000 non-cash impairment charge as well as the absence of $561,000 in accelerated depreciation of leasehold improvements associated with our 2003 restructuring that was taken during the comparative period last year. The decrease was partially offset by increased payroll expenses relating to one-half, or $500,000, of a one-time bonus to our Chief Executive Officer for the achievement of a certain milestone pursuant to his employment agreement. The compensation of our Chief Executive Officer is allocated equally between other research and development expenses and other general and administrative expenses to reflect the allocation of his responsibilities and activities for the company.

We expect our other general and administrative costs to increase modestly over the next year primarily as a result of our support for our clinical development programs, as well as increased costs associated with complying with public company requirements.



Interest and Other Income, Net. Interest and other income, net, increased by $523,000 to $770,000 for the year ended December 31, 2004, as compared to income of $247,000 for the year ended December 31, 2003. The increase resulted from a higher level of invested funds due to the completion of two private placement transactions that closed in November 2003 and February 2004, respectively, as well as due to the general increase in short-term market interest rates when compared to the comparative period last year, partially offset by financing expenses related to notes payable assumed in the acquisition of ACCESS Oncology, which we repaid subsequent to closing the acquisition. In addition, the increase in interest and other income, net was due to a one-time payment of $107,000 from a related party service agreement that terminated in 2004.

Income Taxes. Income tax expense increased by $28,000 to $1,000 for the year ended December 31, 2004, as compared to a credit of $27,000 for year ended December 31, 2003. Our income tax expense for the year ended December 31, 2004, results from state taxes imposed on our capital. Our income tax expense of negative $27,000 for the year ended December 31, 2003, was primarily due to the reversal of taxable income recorded in one of our Israeli subsidiaries partially offset by the elimination of net deferred tax assets of our Israeli subsidiaries, associated with the cessation of our activities in Israel. The reversal of taxable income and the write-off were non-recurring items.

Years Ended December 31, 2003 and 2002

Revenue. We did not have any revenue for the years ended December 31, 2003 and December 31, 2002.

Cost of Services Expense. We did not have any cost of services expenses for the years ended December 31, 2003 and December 31, 2002.

Non-cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants and warrant issuances was negative $486,000 for the year ended December 31, 2003 as compared to negative $1,382,000 for the year ended December 31, 2002. This negative non-cash compensation expense was primarily due to the reversal of previously recorded compensation expense of milestone-based options of $526,000 following the termination of a license agreement.

Non-Cash Acquired In-Process Research and Development Expense. We did not have any non-cash acquired in-process research and development expenses for the years ended December 31, 2003 and December 31, 2002.

Other Research and Development Expenses. Other research and development expenses decreased by $3,527,000 to $5,996,000 for the year ended December 31, 2003, as compared to expenses of $9,523,000 for the year ended December 31, 2002. The decrease in research and development expenses was due primarily to a $2,033,000 reduction in payroll and related costs and a $3,918,000 reduction in lab-related expenses, technology license payments, sponsored research, pre-clinical and consulting fees associated primarily with early stage research and development projects, as a result of the 2003 and 2002 restructurings, as well as the cessation of clinical trial expenses associated with the KRX-101 HIVAN trial in South Africa that was terminated in 2002. These decreases were partially offset by the non-cash impairment charge of $2,358,000 associated with our decision to cease our Jerusalem laboratory activities, as described below and an increase in expenses related to the preparation and initiation of our U.S.-based clinical program for KRX-101.

Non-cash Compensation Expense (General and Administrative). Non-cash compensation expense related to stock option grants was $188,000 for the year ended December 31, 2003 as compared to negative $4,000 for the year ended December 31, 2002. This increase in non-cash compensation expense was primarily due to the revaluation of previously issued options to consultants.

Other General and Administrative Expenses. Other general and administrative expenses decreased by $424,000 to $3,684,000 for the year ended December 31, 2003, as compared to expenses of $4,108,000 for

the year ended December 31, 2002. The decrease in general and administrative expenses was due primarily to a $1,125,000 reduction in payroll and related costs as a result of reduced personnel associated with the 2003 restructuring and the 2002 restructuring. The decrease in general and administrative expenses was partially offset by $561,000 of accelerated depreciation of leasehold improvements in the Jerusalem facility, increased business development expenses, and a $124,000 non-cash impairment charge associated with our decision to sell certain fixed assets located in the Jerusalem facility.

Interest and Other Income, Net. Interest and other income, net, decreased by $266,000 to $247,000 for the year ended December 31, 2003, as compared to income of $513,000 for the year ended December 31, 2002. The decrease resulted from a lower level of invested funds and the general decline in market interest rates when compared to the prior year.

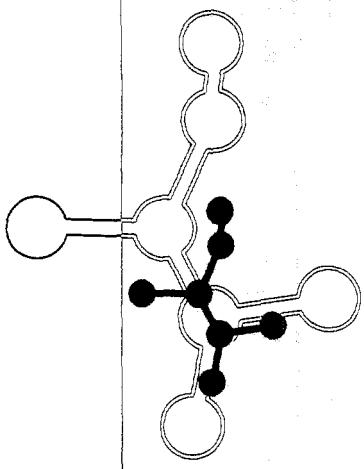
Income Taxes. Income tax expense decreased by $78,000 to a credit of $27,000 for the year ended December 31, 2003, as compared to expenses of $51,000 for the year ended December 31, 2002. The decrease in income tax expense was primarily due to the reversal of taxable income recorded in one of our Israeli subsidiaries partially offset by the elimination of net deferred tax assets of our Israeli subsidiaries, associated with the cessation of our activities in Israel. Income tax expense for the comparative period is attributable to taxable income from the continuing operations of our subsidiaries in Israel.

2003 AND 2002 RESTRUCTURINGS

In 2003, we implemented and completed a strategic reorganization, which we sometimes refer to as the "2003 restructuring." As a result of this reorganization, we ceased all early-stage research and development activities, ceased operations in our Jerusalem lab facility and completed the disposition of our fixed assets in Israel. The 2003 restructuring included a 17-person reduction in our workforce, primarily in Israel. As part of the 2003 restructuring, we reevaluated our long-lived assets in accordance with SFAS No. 144 and recorded a non-cash impairment charge of $2,482,000 for the year ended December 31, 2003, of which $2,358,000 was included in research and development expenses and $124,000 was included in general and administrative expenses. The impairment charge included a write-off of $1,695,000 in fixed assets and $787,000 in intangible assets. In addition, with our decision to vacate the Jerusalem facility, we reevaluated and significantly shortened the useful life of the leasehold improvements associated with our administrative facilities, resulting in accelerated depreciation of $561,000 for the year ended December 31, 2003. In addition, upon vacating the facility in Jerusalem, the landlord of that facility claimed a bank guarantee in the amount of $222,000 that was previously provided as security in connection with the lease agreement. At December 31, 2004 and 2003, respectively, there were no liabilities associated with the 2003 restructuring accrued for on our balance sheet.

During 2002, we implemented a strategic reorganization, which was designed to substantially reduce early stage research expenditures, which we sometimes refer to as the "2002 restructuring." The 2002 restructuring included a 46-person reduction in our workforce, primarily in Israel. As part of the restructuring, we took a charge in 2002 of $228,000, relating to severance not accrued as part of its ongoing accrual made for employee severance benefits throughout the employment term in accordance with Israeli law, $79,000 of which was included in research and development expenses and $149,000 of which was included in general and administrative expenses. As of December 31, 2003, $82,000 in severance obligations related to the 2002 restructuring was included in accrued compensation and related liabilities and was subsequently paid during the first quarter of 2004. At December 31, 2004, there were no liabilities associated with the 2002 restructuring accrued for on our balance sheet.

The following table summarizes restructuring expenses that were incurred by us in 2003 and 2002 that were not part of our ongoing accrual for employee severance benefits made throughout the employment term in accordance with Israeli law. No restructuring expenses were incurred in 2004.



(in thousands)	2004	2003	2002
Other research and development:			
Impairment charge	$ —	$ 2,358	$ —
Realization of bank guarantee in connection with lease agreement	—	144	—
Severance charge	—	4	79
Total other research and development	—	2,506	79
Other general and administrative:			
Impairment charge	—	124	—
Realization of bank guarantee in connection with lease agreement	—	78	—
Severance charge	—	—	149
Accelerated depreciation	—	561	—
Total other general and administrative	—	763	149
Total	$ —	$ 3,269	$ 228

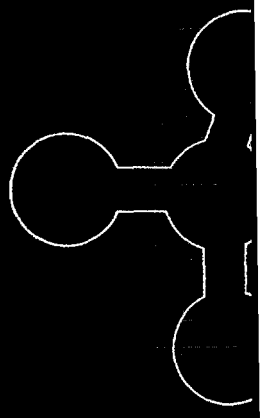
LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations from inception primarily through our initial public offering, various private placement transactions, and option and warrant exercises. As of December 31, 2004, we had received net proceeds of $46.3 million from our initial public offering, net proceeds of approximately $60.4 million from private placements of common and preferred stock and convertible notes, including the conversion of $3.2 million of loans into contributed capital, and proceeds of $5.3 million from the exercise of options and warrants.

We believe that the funds raised will provide us with capital to support our current and planned clinical programs for KRX-101, KRX-0401 and our other oncology drug candidates within our portfolio for approximately the next 24 to 30 months. Additionally, we also believe that our cash position provides us with added flexibility in our in-licensing and product acquisition program to strengthen our portfolio with additional clinical-stage drug candidates.

As of December 31, 2004, we had $49.9 million in cash, cash equivalents, interest receivable, and short-term securities, an increase of $18.5 million from December 31, 2003. Cash used in operating activities for the year ended December 31, 2004 was $12.0 million, as compared to $7.3 million for the year ended December 31, 2003. This increase in cash used in operating activities was due primarily to increased expenditures associated with the execution of our business plan as well as the payment of certain liabilities assumed in the acquisition of ACCESS Oncology. For the year ended December 31, 2004, net cash used in investing activities of $10.4 million was primarily the result of the purchase of investment securities following the private placement transaction that closed in February 2004. For the year ended December 31, 2004, net cash provided by financing activities of $30.4 million was primarily the result of the net proceeds of $31.7 million and $5.0 million generated from our private placement transaction that closed in February 2004 and the exercise of options and warrants, respectively, offset by the payment of notes payable and accrued interest assumed in the acquisition of ACCESS Oncology.

We believe that our $49.9 million in cash, cash equivalents, interest receivable and short-term securities as of December 31, 2004 will be sufficient to enable us to meet our planned operating needs and capital expenditures for approximately the next 24 to 30 months. Our cash and cash equivalents and short-term securities as of December 31, 2004 are invested in highly liquid investments such as cash, money market accounts and short-term U.S. corporate, government debt and auction notes securities. As of December 31, 2004, we are unaware of any known trends or any known demands, commitments, events, or uncertainties that will, or that are reasonably like-



ly to, result in a material increase or decrease in our required liquidity. We expect that our liquidity needs throughout 2005 will continue to be funded from existing cash, cash equivalents, and short-term securities.

On September 29, 2004, we filed a shelf registration statement on Form S-3 with the SEC, which the SEC declared effective on October 13, 2004. The registration statement provides for the offering of up to five million shares of our common stock. We may offer these securities from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interest of the company and our stockholders. We believe that the availability to conduct such offerings enhances our ability to raise additional capital to finance our operations.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

OBLIGATIONS AND COMMITMENTS

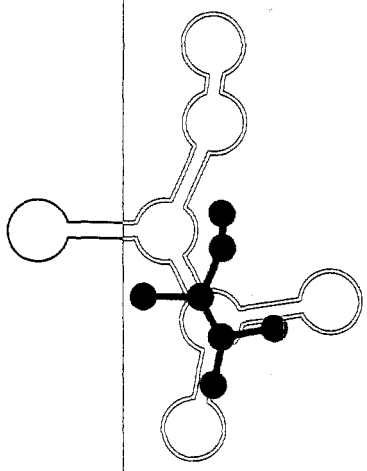
As of December 31, 2004, we have known contractual obligations, commitments and contingencies of $6,888,000. Of this amount, $3,867,000 relates to research and development agreements (primarily relating to our U.S.-based clinical program for KRX-101), of which $3,235,000 is due within the next year, with the remaining balance due as per the schedule below. The additional $3,021,000 relates to our current and recently signed operating lease obligations, of which $237,000 is due within the next year, with the remaining balance due as per the schedule below. In September 2004, we signed a new lease agreement in the same building for our corporate headquarters in New York City for approximately 11,700 square feet, over a period of 5.5 years, at an average rent of approximately $542,000 per year. The new lease will supersede our current lease, which will expire upon our occupation of the new space.

	Payment due by period				
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Research and development agreements	$ 3,867,000	$ 3,235,000	$ 632,000	$ —	$ —
Operating leases	3,021,000	237,000	1,193,000	1,193,000	398,000
Total	$ 6,888,000	$ 3,472,000	$ 1,825,000	$ 1,193,000	$ 398,000

Additionally, we have undertaken to make contingent milestone payments to certain of our licensors of up to approximately $62.4 million over the life of the licenses, of which approximately $43.3 million will be due upon or following regulatory approval of the drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, we remain obligated to pay one licensor $50,000 annually until the license expires. We have also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights if its drug candidates meet development milestones. In addition, pursuant to an employment agreement, our Chief Executive Officer is entitled to receive a one-time $2.0 million performance-based cash bonus upon the achievement of a certain market capitalization or working capital milestone event. These commitments are not included in the table above.

CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting princi-



ples. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

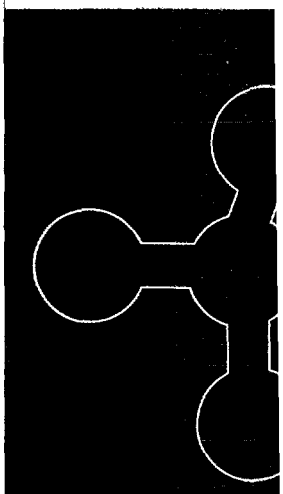
Stock Compensation. We have granted options to employees, directors and consultants, as well as warrants to other third parties. In applying Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," or SFAS No. 123, we use the Black-Scholes pricing model to calculate the fair market value of our options and warrants. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option or warrant, the closing market price of our stock and the exercise price. We have assumed for the purposes of the Black-Scholes calculation that an option will be exercised one year and two years after it fully vests for consultants and employees, respectively. We base our estimates of our stock price volatility on the volatility during the period prior to the grant of the option or warrant; however, this estimate is neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants.

In accordance with EITF 96-18 "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," total compensation expense for options issued to consultants is determined at the "measurement date." The expense is recognized over the vesting period for the options. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record option compensation based on the fair value of the options at the reporting date. These options are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the option grant, and additional expense or a negative expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

We account for stock-based employee and director compensation arrangements in accordance with the provisions of APB Opinion No. 25, "Accounting for Stock Issued to Employees," or APB 25, and the Financial Accounting Standards Board, or FASB, Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation," or FIN 44, as allowed by SFAS No. 123. We also comply with the disclosure provisions of SFAS No. 123 and SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure," or SFAS No. 148.

Accounting Related to the Valuation of Acquired In-Process Research and Development. As required by Financial Accounting Standards Board Interpretation No. 4, "Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method," or FIN 4, we recorded a charge of $18,800,000 for the estimate of the portion of the ACCESS Oncology purchase price allocated to acquired in-process research and development.

A project-by-project valuation using the guidance in Statement of Financial Accounting Standards No. 141, "Business Combinations" and the AICPA Practice Aid "Assets Acquired in a Business Combination to Be Used In Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries" was performed with the assistance of independent valuation specialists to determine the fair value of research and development projects of ACCESS Oncology which were in-process, but not yet completed.



The fair value was determined using the income approach on a project-by-project basis. This method starts with a forecast of the expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the project's stage of completion and other risk factors. These other risk factors can include the nature of the product, the scientific data associated with the technology, the current patent situation and market competition.

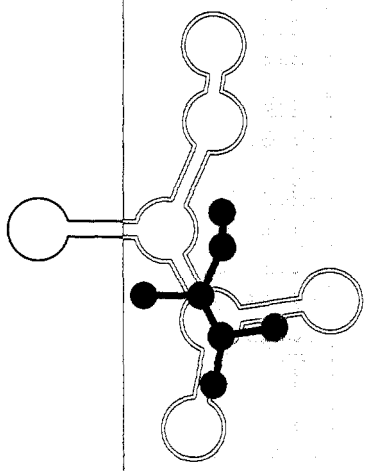
The forecast of future cash flows required the following assumptions to be made:

- revenue that is likely to result from specific in-process research and development projects, including estimated patient populations, estimated selling prices, estimated market penetration and estimated market share and year-over-year growth rates over the product life cycles;
- cost of sales related to the potential products using industry data or other sources of market data;
- sales and marketing expense using industry data or other market data;
- general and administrative expenses; and
- research and development expenses.

The valuations are based on information that were available as of the acquisition date and the expectations and assumptions deemed reasonable by our management. No assurance can be given, however, that the underlying assumptions or events associated with such assets will occur as projected. For these reasons, among others, the actual results may vary from the projected results.

Accounting For Income Taxes. In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the statement of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our U.S. deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in establishing the valuation allowance. In prior periods, our wholly-owned Israeli subsidiaries had generated taxable income in respect of services provided within the group, and therefore we believed in the past that our deferred tax assets relating to the Israeli subsidiaries would be realized. With the cessation of operating activities in Israel during 2003 and the resulting absence of taxable income from the Israeli subsidiaries, the deferred tax asset was written off in 2003. Our current income tax expense results from state taxes imposed on our capital.

Impairment. We have adopted SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," or SFAS No. 144, since January 1, 2002. SFAS No. 144 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.



RECENTLY ISSUED ACCOUNTING STANDARDS

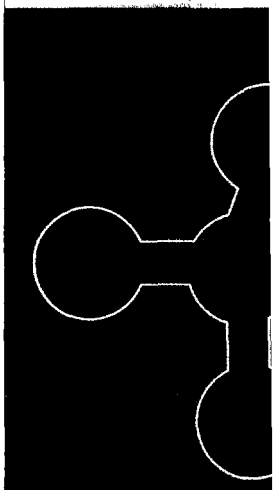
In December 2004, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 123R, Share-Based Payment. SFAS 123R replaces SFAS 123, Stock-Based Compensation, issued in 1995. SFAS 123R requires that the fair value of the grant of employee stock options be reported as an expense. Historically, we have disclosed in our footnotes the pro forma expense effect of stock options granted under our stock option plans in Note 1, Organization and Summary of Significant Accounting Policies: Stock-Based Compensation. We plan to adopt SFAS 123R when required in the third quarter of 2005. The estimated impact of adopting SFAS 123R will have a material impact on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in government and investment-grade corporate debt and auction notes securities in accordance with our investment policy. Some of these securities in which we invest may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. As of December 31, 2004, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including corporate debt, money market funds, government debt and auction notes securities. The average duration of all of our held-to-maturity investments held as of December 31, 2004, was less than one year. The re-pricing of our auction notes within thirty days allows these securities to function as short-term investments. Due to the short-term nature of all of our investments, we believe we have no material exposure to interest rate risk arising from our investments.

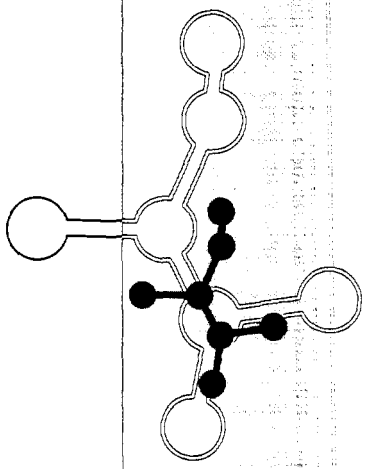
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements as of December 31, 2004, are included in Item 15 of this report and are presented beginning on page F-1 of this report. The following table sets forth unaudited selected operating results for each of the four fiscal quarters in the years ended December 31, 2004, and December 31, 2003. We believe that the following selected quarterly information includes all adjustments, consisting only of normal, recurring adjustments, which we consider necessary to present this information fairly. You should read this financial information in conjunction with the financial statements and related notes appearing elsewhere in this report. Our results of operations have fluctuated in the past and are likely to continue to fluctuate greatly from quarter to quarter in the future. Therefore, results of operations for any previous periods are not necessarily indicative of results of operations to be recorded in the future.



(in thousands, except per share data)	2004 Mar. 31	June 30	Sept. 30	Dec. 31
Service revenue	$ 95	$ 150	$ 397	$ 167
Operating expenses:				
Cost of services	80	123	416	216
Research and development:				
Non-cash compensation	202	23	70	118
Non-cash acquired in-process research and development	18,800	—	—	—
Other research and development	1,652	2,067	2,594	3,492
Total research and development	20,654	2,090	2,664	3,610
General and administrative:				
Non-cash compensation	185	621	161	120
Other general and administrative	1,093	745	596	1,147
Total general and administrative	1,278	1,366	757	1,267
Total operating expenses	22,012	3,579	3,837	5,093
Operating loss	(21,917)	(3,429)	(3,440)	(4,926)
Other income (expense)				
Interest and other income, net	95	170	187	318
Income taxes	(1)	—	—	—
Net loss	$ (21,823)	$ (3,259)	$ (3,253)	$ (4,608)
Net loss per common share				
Basic and diluted	$ (0.78)	$ (0.11)	$ (0.11)	$ (0.15)

(in thousands, except per share data)	2003 Mar. 31	June 30	Sept. 30	Dec. 31
Service revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Cost of services	—	—	—	—
Research and development:				
Non-cash compensation	(266)	(249)	—	29
Non-cash acquired in-process research and development	—	—	—	—
Other research and development	3,371	554	810	1,261
Total research and development	3,105	305	810	1,290
General and administrative:				
Non-cash compensation	2	50	17	119
Other general and administrative	664	1,205	763	1,052
Total general and administrative	666	1,255	780	1,171
Total operating expenses	3,771	1,560	1,590	2,461
Operating loss	(3,771)	(1,560)	(1,590)	(2,461)
Other income (expense)				
Interest and other income, net	85	65	34	63
Income taxes	(102)	(14)	—	143
Net loss	$ (3,788)	$ (1,509)	$ (1,556)	$ (2,255)
Net loss per common share				
Basic and diluted	$ (0.19)	$ (0.07)	$ (0.07)	$ (0.10)



ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. Based on their evaluation as of December 31, 2004, our Chief Executive Officer and Principal Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective to ensure that the information required to be disclosed by us in our reports that we file or submit to the SEC was recorded, processed, summarized and reported properly, within the time periods specified in the SEC's rules and forms.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework. Our management has concluded that, as of December 31, 2004, our internal control over financial reporting is effective based on these criteria. Our independent registered public accounting firm, KPMG LLP, issued an attestation on our assessment of our internal control over financial reporting, which is included herein.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2004, that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Principal Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY

The information required by this Item regarding our directors and officers is incorporated herein by reference from our Proxy Statement for our 2005 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item regarding executive compensation is incorporated herein by reference from our Proxy Statement for our 2005 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

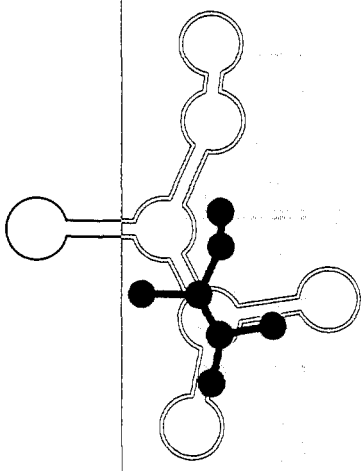
The information required by this Item regarding the security ownership of certain of our beneficial owners and our management is incorporated herein by reference from our Proxy Statement for our 2005 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by this Item regarding certain relationships and related transactions is incorporated herein by reference from our Proxy Statement for our 2005 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item regarding principal accountant fees and services is incorporated herein by reference to our Proxy Statement for our 2005 Annual Meeting of Stockholders.



PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES

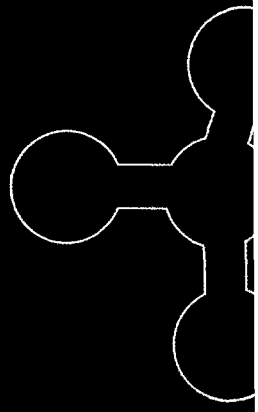
(a) 1. Consolidated Financial Statements

The following consolidated financial statements of Keryx Biopharmaceuticals, Inc. are filed as part of this report.

Contents

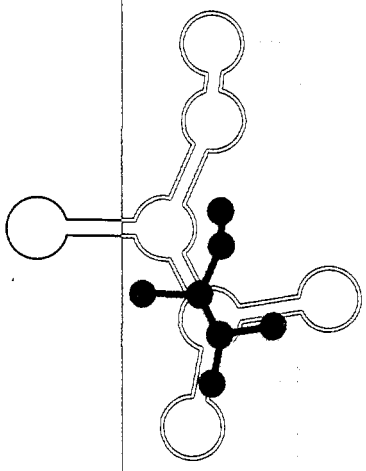
2. Consolidated Financial Statement Schedules

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.



3. Exhibits

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger by and among Keryx Biopharmaceuticals, Inc., AXO Acquisition Corp., and ACCESS Oncology, Inc. dated as of January 7, 2004, filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K dated January 8, 2004 (File No. 000-30929), and incorporated herein by reference.
2.2	First Amendment to the Agreement and Plan of Merger by and among Keryx Biopharmaceuticals, Inc., AXO Acquisition Corp., and ACCESS Oncology, Inc. dated as of February 5, 2004, filed as Exhibit 2.2 to the Registrant's Current Report on Form 8-K dated February 5, 2004 (File No. 000-30929), and incorporated herein by reference.
3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.
4.1	Specimen Common Stock Certificate, filed as Exhibit 4.1 to the Registrant's First Amendment to the Registration Statement on Form S-1 filed on June 30, 2000 (File No. 333-37402), and incorporated herein by reference.
4.2	Form of Warrant for the Purchase of Shares of Common Stock between certain holders of Series A Preferred Stock and Keryx Biopharmaceuticals, Inc., dated as of December 14, 1999, filed as Exhibit 4.9 to the Registrant's Registration Statement on Form S-1 filed on May 19, 2000 (File No. 333-37402), and incorporated herein by reference.
4.3	Form of Common Stock Purchase Warrant dated November 20, 2003, issued to the purchasers under the Securities Purchase Agreement, filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.
4.4	Securities Purchase Agreement dated November 12, 2003 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.
4.5	Registration Rights Agreement dated November 17, 2003 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.
4.6	Securities Purchase Agreement dated February 12, 2004 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed on March 16, 2004 (File No. 333-113654), and incorporated herein by reference
4.7	Registration Rights Agreement dated February 17, 2004 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-3 filed on March 16, 2004 (File No. 333-113654), and incorporated herein by reference.
10.1†	Employment Agreement with I. Craig Henderson, M.D., dated as of January 31, 2004. filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.



10.2† Severance Agreement between Morris Laster, M.D. and Keryx Biopharmaceuticals, Inc., dated February 27, 2003, filed as Exhibit 10.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002 filed on March 31, 2003 (File No. 000-30929), and incorporated herein by reference.

10.3† Severance Agreement between Benjamin Corn, M.D. and Keryx Biopharmaceuticals Inc., dated February 23, 2003, filed as Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002 filed on March 31, 2003 (File No. 333-37402), and incorporated herein by reference.

10.4! License Agreement between Alfa Wassermann S.p.A. and Partec Ltd., dated as of November 12, 1998, filed as Exhibit 10.7 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on July 24, 2000 (File No. 333-37402), and incorporated by reference.

10.5! License Agreement between Opocrin S.p.A. and Keryx Biopharmaceuticals, Inc., dated September 25, 2002, filed as Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 filed on November 12, 2002 (File No. 000-30929), and incorporated herein by reference.

10.6 Form of KRX-101 Scientific Advisory Board Agreement, filed as Exhibit 10.20 to the Registrant's First Amendment to the Registration Statement on Form S-1 filed on June 30, 2000 (File No. 333-37402), and incorporated herein be reference.

10.7 Lease Agreement between RMPA Nechasim, Ltd. and Keryx (Israel) Ltd., dated as of December 21, 2000, filed as Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000 filed on March 30, 2001 (File No. 000-30929), and incorporated herein by reference.

10.8 Sub-lease Agreement between Keryx Biopharmaceuticals, Inc. and Zero Stage Capital, Inc., dated June 20, 2001, filed as Exhibit 10.34 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001 filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.

10.9† Employment Agreement between Ron Bentsur and Keryx Biopharmaceuticals, Inc., dated as of June 23, 2003, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 filed on August 14, 2003 (File No. 000-30929), and incorporated herein by reference.

10.10† Employment Agreement between Keryx Biopharmaceuticals, Inc. and Michael S. Weiss dated as of December 23, 2002, filed as Exhibit 10.1 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929), and incorporated herein by reference.

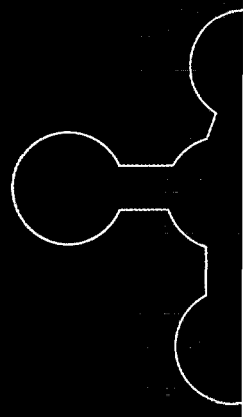
10.11† 1999 Stock Option Plan, as amended, filed as Exhibit 10.2 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929) and incorporated herein by reference.

10.12† 2000 Stock Option Plan, as amended, filed as Exhibit 10.3 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929) and incorporated herein by reference.

10.13† 2002 CEO Incentive Stock Option Plan, filed as Exhibit 10.4 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929) and incorporated herein by reference.

10.14† Employment Agreement with I. Craig Henderson, M.D., dated January 1, 2001, filed as Exhibit 10.31 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.15 Sub-license Agreement dated October 13, 2000 between Procept, Inc. and AOI Pharmaceuticals, Inc., filed as Exhibit 10.32 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.



10.16 Amendment to Sub-license agreement dated February 28, 2002 between AOI Pharmaceuticals, Inc. and Procept, Inc., filed as Exhibit 10.33 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.17 Patent License Agreement dated February 28, 2002 between Procept, Inc. and United State Public Health Services, as amended, filed as Exhibit 10.34 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.18 Release Agreement dated February 28, 2002 among AOI Pharmaceuticals, Inc., Procept, Inc., and United States Public Health Services, filed as Exhibit 10.35 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.19 Comprehensive Release Agreement dated May 29, 2002 among AOI Pharmaceuticals, Inc., Procept, Inc., United States Public Health Services and the University of Chicago, filed as Exhibit 10.36 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.20! Sub-license Agreement between Prescient NeuroPharma, Inc. and ACCESS Oncology, Inc. dated December 24, 2001, filed as Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference. .

10.21! License Agreement dated September 18, 2002 between Zentaris AG and AOI Pharma, Inc, filed as Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.22! Addendum Agreement to License and Cooperation Agreement for Perifosine dated December 3, 2003 between Zentaris AG and AOI Pharma, Inc., filed as Exhibit 10.39 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.23 Cooperative Research and Development Agreement between the National Cancer Institute and ASTA Medica Inc., as amended, filed as Exhibit 10.40 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

10.24 Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan, filed with the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders on June 10, 2004, filed on April 29, 2004, and incorporated herein by reference.

21.1 List of subsidiaries of Keryx Biopharmaceuticals, Inc.

23.1 Consent of KPMG LLP.

24.1 Power of Attorney of Director and Officers of Keryx Biopharmaceuticals, Inc. (included herein).

31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 14, 2005.

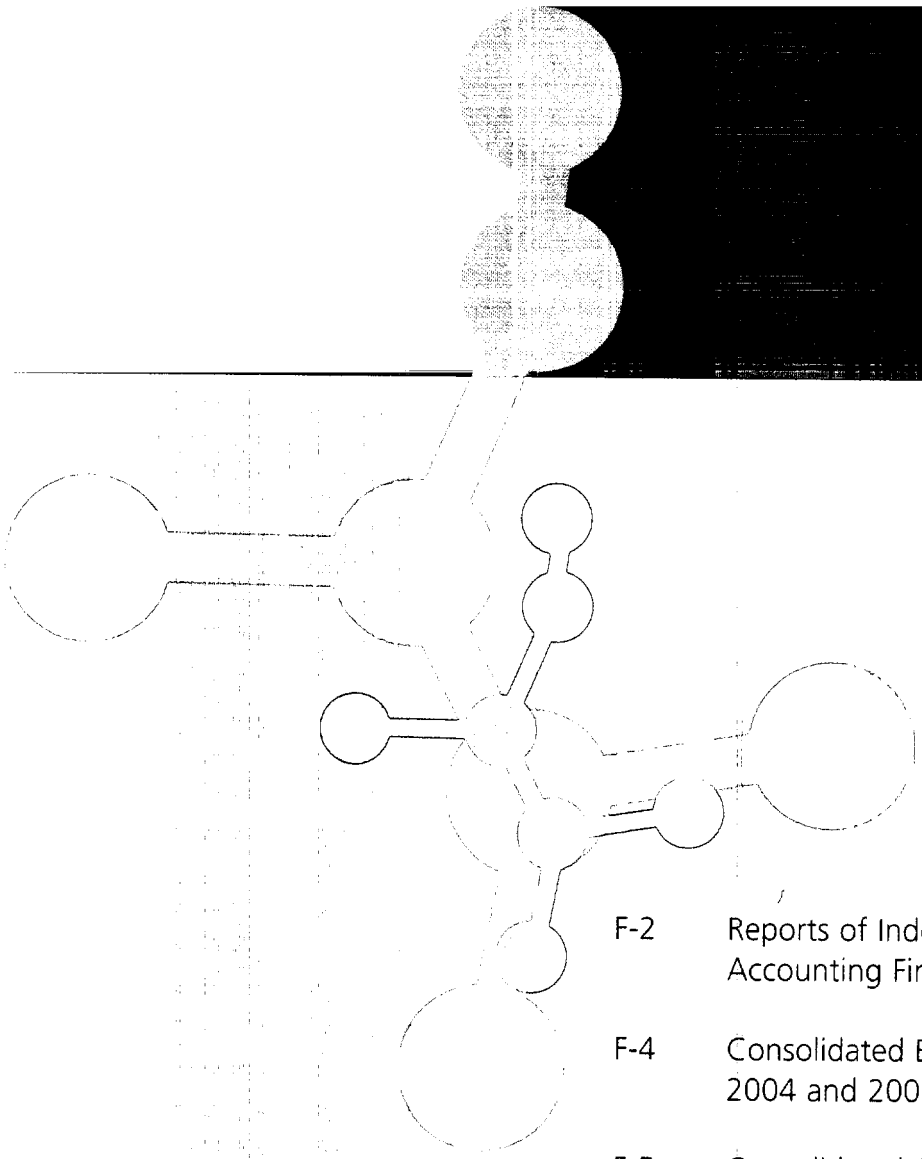
31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 14, 2005.

32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 14, 2005.

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 14, 2005.

! Confidential treatment has been granted with respect to the omitted portions of this exhibit.

† Indicates management contract or compensatory plan or arrangement.



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Keryx Biopharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of Keryx Biopharmaceuticals, Inc. and subsidiaries (the "Company"), a development stage company, as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and for the period from December 3, 1996 to December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Keryx Biopharmaceuticals, Inc. and subsidiaries, a development stage company, as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, and for the period from December 3, 1996 to December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 14, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

New York, New York

March 14, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Keryx Biopharmaceuticals, Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Keryx Biopharmaceuticals, Inc. and subsidiaries (the "Company"), a development stage company, maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on, criteria established in Internal Control-Integrated Framework issued by the COSO. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and for the period from December 3, 1996 to December 31, 2004, and our report dated March 14, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

New York, New York

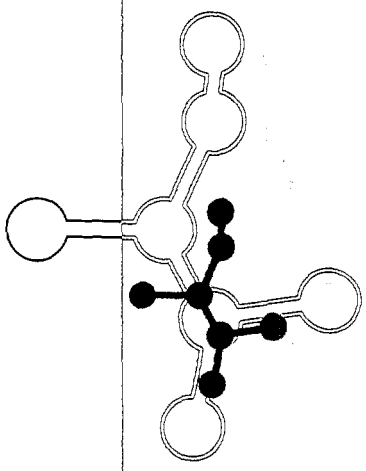
March 14, 2005

CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31
(in thousands, except share and per share amounts)

	2004	2003
Assets		
Current assets		
Cash and cash equivalents	**$ 29,699**	$ 21,672
Short-term investment securities	**20,035**	9,631
Note and accrued interest receivable from related party	**—**	352
Accrued interest receivable	**144**	111
Other receivables and prepaid expenses	**622**	213
Total current assets	**50,500**	31,979
Property, plant and equipment, net	**145**	24
Other assets (primarily intangible assets), net	**217**	220
Total assets	**$ 50,862**	$ 32,223
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	**$ 3,079**	$ 894
Accrued compensation and related liabilities	**743**	103
Deferred revenue	**140**	—
Total current liabilities	**3,962**	997
Contingent equity rights	**4,004**	—
Other liabilities	**92**	—
Total liabilities	**8,058**	997
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, $0.001 par value per share (60,000,000 and 40,000,000 shares authorized, 31,373,280 and 25,016,873 shares issued, 31,317,180 and 24,960,773 shares outstanding at December 31, 2004, and 2003, respectively)	**31**	25
Additional paid-in capital	**132,643**	86,042
Treasury stock, at cost, 56,100 shares at December 31, 2004, and 2003, respectively	**(89)**	(89)
Unearned compensation	**(2,228)**	(142)
Deficit accumulated during the development stage	**(87,553)**	(54,610)
Total stockholders' equity	**42,804**	31,226
Total liabilities and stockholders' equity	**$ 50,862**	$ 32,223

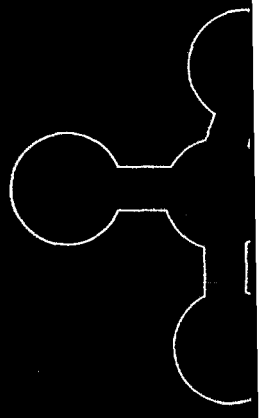
The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31 (in thousands, except share and per share amounts)



	2004	2003	2002	Amounts accumulated during the development stage
Revenue:				
Service revenue	**$ 809**	$ —	$ —	$ 809
Management fees from related party	**—**	—	—	300
Total revenue	**809**	—	—	1,109
Operating expenses:				
Cost of services	**835**	—	—	835
Research and development:				
Non-cash compensation	**413**	(486)	(1,382)	7,140
Non-cash acquired in-process research and development	**18,800**	—	—	18,800
Other research and development	**9,805**	5,996	9,523	39,712
Total research and development expenses	**29,018**	5,510	8,141	65,652
General and administrative:				
Non-cash compensation	**1,087**	188	(4)	4,666
Other general and administrative	**3,581**	3,684	4,108	21,670
Total general and administrative expenses	**4,668**	3,872	4,104	26,336
Total operating expenses	**34,521**	9,382	12,245	92,823
Operating loss	**(33,712)**	(9,382)	(12,245)	(91,714)
Interest and other income, net	**770**	247	513	4,652
Net loss before income taxes	**(32,942)**	(9,135)	(11,732)	(87,062)
Income taxes	**1**	(27)	51	491
Net loss	**$ (32,943)**	$ (9,108)	$ (11,783)	$ (87,553)
Basic and diluted loss per common share	**$ (1.10)**	$ (0.43)	$ (0.59)	$ (5.46)
Weighted average shares used in computing basic and diluted net loss per common share	**30,053,647**	21,367,088	19,897,939	16,037,815

The accompanying notes are an integral part of the consolidated financial statements.



CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Series A convertible preferred stock		Common stock		Additional paid-in capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2001	—	$ —	19,846,694	$ 19	$ 74,025
Changes during the year:					
Issuance of common stock to technology licensors for technology license	—	—	48,491	1	358
Purchase of common stock	—	—	—	—	—
Exercise of warrants	—	—	—	—	—
Exercise of options	—	—	18,000	—*	2
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	—	—	(2,318)
Net loss	—	—	—	—	—
Balance at December 31, 2002	—	$ —	19,913,185	$ 20	$ 72,067

	Treasury stock		Unearned compensation	Deficit accumulated during the development stage	Total
	Shares	Amount			
Balance at December 31, 2001	—	$ —	$ (1,110)	$ (33,719)	$ 39,215
Changes during the year:					
Issuance of common stock to technology licensors for technology license	—	—	—	—	359
Purchase of common stock	46,300	(77)	—	—	(77)
Exercise of warrants	—	—	—	—	—
Exercise of options	—	—	—	—	2
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	932	—	(1,386)
Net loss	—	—	—	(11,783)	(11,783)
Balance at December 31, 2002	46,300	$ (77)	$ (178)	$ (45,502)	$ 26,330

* Amount less than one thousand dollars.

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(CONTINUED) (in thousands, except share amounts)

	Series A convertible preferred stock		Common stock		Additional paid-in capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2002	—	$ —	19,913,185	$ 20	$ 72,067
Changes during the year:					
Issuance of common stock in private placement (net of issuance expenses of $867)	—	—	3,529,412	3	14,130
Purchase of common stock	—	—	—	—	—
Exercise of options	—	—	1,574,276	2	179
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	—	—	(334)
Net loss	—	—	—	—	—
Balance at December 31, 2003	—	$ —	25,016,873	$ 25	$ 86,042

	Treasury stock		Unearned compensation	Deficit accumulated during the development stage	Total
	Shares	Amount			
Balance at December 31, 2002	46,300	$ (77)	$ (178)	$ (45,502)	$ 26,330
Changes during the year:					
Issuance of common stock in private placement (net of issuance expenses of $867)	—	—	—	—	14,133
Purchase of common stock	9,800	(12)	—	—	(12)
Exercise of options	—	—	—	—	181
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	36	—	(298)
Net loss	—	—	—	(9,108)	(9,108)
Balance at December 31, 2003	56,100	$ (89)	$ (142)	$ (54,610)	$ 31,226

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(CONTINUED) (in thousands, except share amounts)

	Series A convertible preferred stock		Common stock		Additional paid-in capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2003	—	$ —	25,016,873	$ 25	$ 86,042
Changes during the year:					
Issuance of common stock in private placement (net of issuance expenses of $338)	—	—	3,200,000	3	31,659
Issuance of common stock in connection with acquisition	—	—	623,145	1	6,324
Exercise of warrants	—	—	348,824	—*	2,093
Exercise of options	—	—	2,184,438	2	2,939
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	—	—	3,586
Net loss	—	—	—	—	—
Balance at December 31, 2004	—	$ —	31,373,280	$ 31	$ 132,643

	Treasury stock		Unearned compensation	Deficit accumulated during the development stage	Total
	Shares	Amount			
Balance at December 31, 2003	56,100	$ (89)	$ (142)	$ (54,610)	$ 31,226
Changes during the year:					
Issuance of common stock in private placement (net of issuance expenses of $338)	—	—	—	—	31,662
Issuance of common stock in connection with acquisition	—	—	—	—	6,325
Exercise of warrants	—	—	—	—	2,093
Exercise of options	—	—	—	—	2,941
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	(2,086)	—	1,500
Net loss	—	—	—	(32,943)	(32,943)
Balance at December 31, 2004	56,100	$ (89)	$ (2,228)	$ (87,553)	$ 42,804

* Amount less than one thousand dollars.

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(CONTINUED) (in thousands, except share amounts)

	Series A convertible preferred stock		Common stock		Additional paid-in capital
	Shares	Amount	Shares	Amount	
Amounts accumulated during the development stage (December 3, 1996 to December 31, 2004):					
Contributed capital	—	$ —	—	$ —	$ 3,181
Conversion of convertible notes of Partec into stock in Keryx	—	—	—	—	2,973
Issuance of Series A convertible preferred stock to investors at $100 per share for cash (net of issuance expenses of $552)	89,180	—*	—	—	8,338
Issuance of Series A convertible preferred stock at $0.001 par value to note holders in exchange for note of predecessor	29,465	—*	—	—	—
Issuance of common stock to technology licensors for technology license	—	—	1,256,797	2	358
Issuance of common stock in private placement (net of issuance expenses of $1,205)	—	—	6,729,412	6	45,789
Issuance of common stock in connection with acquisition	—	—	623,145	1	6,324
Receipt on account of shares issued in prior years	—	—	6,900,000	7	—
Conversion of Series A convertible preferred stock to common stock	(118,645)	(—)*	6,114,962	6	(6)
Issuance of common stock in initial public offering, including exercise of overallotment (net of issuance expenses of $5,702)	—	—	5,200,000	5	46,293
Purchase of common stock	—	—	—	—	—
Exercise of warrants	—	—	596,250	—*	2,104
Exercise of options	—	—	3,952,714	4	3,143
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	—	—	13,444
Warrants of common stock issued to related party as finder's fee in private placement	—	—	—	—	114
Warrants for common stock issued to note holders in exchange for note of predecessor	—	—	—	—	588
Net loss	—	—	—	—	—
Balance at December 31, 2004	—	$ —	31,373,280	$ 31	$ 132,643

* Amount less than one thousand dollars.

The accompanying notes are an integral part of the consolidated financial statements.

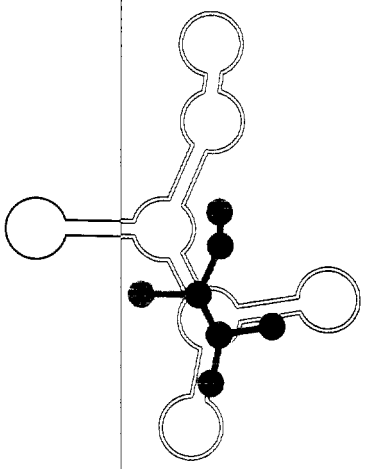
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(CONTINUED) (in thousands, except share amounts)

	Treasury stock		Unearned compensation	Deficit accumulated during the development stage	Total
	Shares	Amount			
Amounts accumulated during the development stage (December 3, 1996 to December 31, 2004):					
Contributed capital	—	$ —	$ —	$ —	$ 3,181
Conversion of convertible notes of Partec into stock in Keryx	—	—	—	—	2,973
Issuance of Series A convertible preferred stock to investors at $100 per share for cash (net of issuance expenses of $552)	—	—	—	—	8,338
Issuance of Series A convertible preferred stock at $0.001 par value to note holders in exchange for note of predecessor	—	—	—	—	—*
Issuance of common stock to technology licensors for technology license	—	—	—	—	360
Issuance of common stock in private placement (net of issuance expenses of $1,205)	—	—	—	—	45,795
Issuance of common stock in connection with acquisition	—	—	—	—	6,325
Receipt on account of shares issued in prior years	—	—	—	—	7
Conversion of Series A convertible preferred stock to common stock	—	—	—	—	(—)*
Issuance of common stock in initial public offering, including exercise of overallotment (net of issuance expenses of $5,702)	—	—	—	—	46,298
Purchase of common stock	56,100	(89)	—	—	(89)
Exercise of warrants	—	—	—	—	2,104
Exercise of options	—	—	—	—	3,147
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	(2,228)	—	11,216
Warrants of common stock issued to related party as finder's fee in private placement	—	—	—	—	114
Warrants for common stock issued to note holders in exchange for note of predecessor	—	—	—	—	588
Net loss	—	—	—	(87,553)	(87,553)
Balance at December 31, 2004	56,100	$ (89)	$ (2,228)	$ (87,553)	$ 42,804

* Amount less than one thousand dollars.

The accompanying notes are an integral part of the consolidated financial statements.



CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31 (in thousands)

	2004	2003	2002	Amounts accumulated during the development stage
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	**$ (32,943)**	$ (9,108)	$ (11,783)	$ (87,553)
Adjustments to reconcile cash flows used in operating activities:				
Acquired in-process research and development	**18,800**	—	—	18,800
Stock compensation expense (negative expense)	**1,500**	(298)	(1,386)	11,806
Issuance of common stock to technology licensor	**—**	—	359	359
Interest on convertible notes settled through issuance of preferred shares	**—**	—	—	253
Depreciation and amortization	**155**	940	953	2,421
Loss on disposal of property, plant and equipment	**—**	86	56	170
Impairment charges	**—**	2,482	—	2,482
Exchange rate differences	**(3)**	13	26	94
Changes in assets and liabilities, net of effects of acquisitions:				
Decrease (increase) in other receivables and prepaid expenses	**(43)**	54	198	(251)
Decrease (increase) in accrued interest receivable	**(33)**	95	(3)	(144)
Changes in deferred tax provisions and valuation allowance	**—**	102	13	—
Increase (decrease) in accounts payable and accrued expenses	**874**	22	(750)	1,766
Increase (decrease) in income taxes payable	**—**	(177)	(100)	—
Increase (decrease) in accrued compensation and related liabilities	**68**	(1,317)	710	171
Increase (decrease) in liability in respect of employee severance obligations	**—**	(188)	(578)	—
(Decrease) in other liabilities	**(63)**	—	—	(63)
Increase (decrease) in deferred revenue	**(316)**	—	—	(316)
Net cash used in operating activities	**(12,004)**	(7,294)	(12,285)	(50,005)
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property, plant and equipment	**(24)**	(3)	(1,155)	(4,427)
Proceeds from disposals of property, plant and equipment	**—**	387	37	424
Decrease (increase) in note and accrued interest receivable from related party	**(4)**	(352)	—	(356)
Investment in other assets	**(8)**	(65)	(99)	(1,196)
Proceeds from (additions to) deposits in respect of employee severance obligations	**—**	416	(125)	—
Proceeds from sale and maturity of (investment in) held-to-maturity short-term securities	**(5,379)**	944	3,733	(15,010)
Investment in available-for-sale short-term securities	**(6,025)**	—	—	(6,025)
Proceeds from sale of available-for-sale short-term securities	**1,000**	—	—	1,000
Net cash provided by (used in) investing activities	**(10,440)**	1,327	2,391	(25,590)

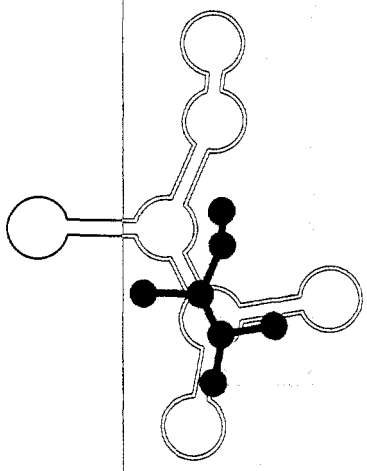
The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31 (CONTINUED) (in thousands)

	2004	2003	2002	Amounts accumulated during the development stage
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from short-term loans	**$ —**	$ —	$ —	$ 500
Proceeds from long-term loans	**—**	—	—	3,251
Payment of assumed notes payable and accrued interest in connection with the ACCESS Oncology acquisition	**(6,322)**	—	—	(6,322)
Issuance of convertible note, net	**—**	—	—	2,150
Issuance of preferred shares, net	**—**	—	—	8,453
Receipts on account of shares previously issued	**—**	—	—	7
Proceeds from initial public offering, net	**—**	—	—	46,298
Proceeds from private placements, net	**31,662**	14,133	—	45,795
Proceeds from exercise of options and warrants	**5,034**	181	2	5,251
Purchase of treasury stock	**—**	(12)	(77)	(89)
Net cash provided by (used in) financing activities	**30,374**	14,302	(75)	105,294
Cash acquired in acquisition	**94**	—	—	94
Effect of exchange rate on cash	**3**	(13)	(26)	(94)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**8,027**	8,322	(9,995)	29,699
Cash and cash equivalents at beginning of year	**21,672**	13,350	23,345	—
CASH AND CASH EQUIVALENTS AT END OF YEAR	**$ 29,699**	$ 21,672	$ 13,350	$ 29,699
NON - CASH TRANSACTIONS				
Issuance of common stock in connection with acquisition	**$ 6,325**	$ —	$ —	$ 6,325
Issuance of contingent equity rights in connection with acquisition	**4,004**	—	—	4,004
Assumption of liabilities in connection with acquisition	**8,723**	—	—	8,723
Conversion of short-term loans into contributed capital	**—**	—	—	500
Conversion of long-term loans into contributed capital	**—**	—	—	2,681
Conversion of long-term loans into convertible notes of Partec	**—**	—	—	570
Conversion of convertible notes of Partec and accrued interest into stock in Keryx	**—**	—	—	2,973
Issuance of warrants to related party as finder's fee in private placement	**—**	—	—	114
Declaration of stock dividend	**—**	—	—	3
Purchase of property, plant and equipment and other assets on credit	**—**	—	47	—
SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION				
Cash paid for interest	**$ 1,026**	$ 1	$ —*	$ 1,166
Cash paid for income taxes	**$ 1**	$ 60	$ 132	$ 432

* Amount less than one thousand dollars.

The accompanying notes are an integral part of the consolidated financial statements.



NOTE 1 - ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

DESCRIPTION OF BUSINESS

Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") is a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. The Company was incorporated in Delaware in October 1998 (under the name Paramount Pharmaceuticals, Inc., which was later changed to Lakaro Biopharmaceuticals, Inc. in November 1999, and finally to Keryx Biopharmaceuticals, Inc. in January 2000). The Company commenced activities in November 1999, and since then has operated in one segment of operations, namely the development and commercialization of clinical compounds and core technologies for the life sciences.

Until November 1999, most of the Company's activities were carried out by Partec Limited, an Israeli corporation formed in December 1996, and its subsidiaries SignalSite Inc. (85% owned), SignalSite Israel Ltd. (wholly-owned), Vectagen Inc. (87.25% owned) and Vectagen Israel Ltd. (wholly-owned) (hereinafter collectively referred to as "Partec"). In November 1999, the Company acquired substantially all of the assets and liabilities of Partec and, as of that date, the activities formerly carried out by Partec were performed by the Company. On the date of the acquisition, Keryx and Partec were entities under common control (the controlling interest owned approximately 79.7% of Keryx and approximately 76% of Partec) and accordingly, the assets and liabilities were recorded at their historical cost basis by means of an "as if" pooling, with Partec being presented as a predecessor company. Consequently, these financial statements include the activities performed in previous periods by Partec by aggregating the relevant historical financial information with the financial statements of the Company as if they had formed a discrete operation under common management for the entire development stage.

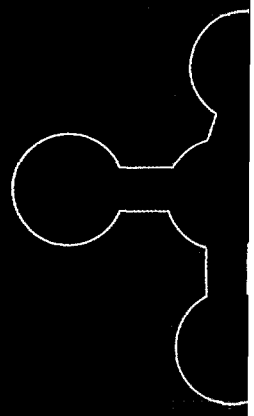
The Company owns a 100% interest in each of ACCESS Oncology, Inc. and Neryx Biopharmaceuticals, Inc., both U.S. corporations incorporated in the State of Delaware, Keryx (Israel) Ltd., organized in Israel, Keryx Biomedical Technologies Ltd., organized in Israel, and K.B.I. Biopharmaceuticals Ltd., organized in Israel. In 2003, the Company's three subsidiaries in Israel ceased operations and are currently in the process of being closed down. Substantially all of the Company's biopharmaceutical development and administrative activities during 2004 and 2003 were conducted in the United States of America.

On February 5, 2004, the Company completed the acquisition of ACCESS Oncology, Inc. and its subsidiaries ("ACCESS Oncology"). The transaction was structured as a merger of AXO Acquisition Corp., a Delaware corporation and the Company's wholly-owned subsidiary, with and into ACCESS Oncology, with ACCESS Oncology remaining as the surviving corporation and a wholly-owned subsidiary of the Company. The transaction was accounted for under the purchase method of accounting. See Note 6 - ACCESS Oncology Acquisition for additional information. The assets and liabilities of ACCESS Oncology that the Company acquired and assumed pursuant to the acquisition have been included in the Company's consolidated financial statements effective February 5, 2004.

The Company has not generated any revenues from its planned principal operations and is dependent upon significant financing to provide the working capital necessary to execute its business plan. If the Company determines it is necessary to seek additional funding, there can be no assurance that the Company will be able to obtain any such funding on terms that are acceptable to it, if at all.

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.



USE OF ESTIMATES

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to the financial statements.

The Company believes its application of accounting policies, and the estimates inherently required therein, are reasonable. These accounting policies and estimates are regularly reevaluated, and adjustments are made when facts and circumstances dictate a change. Historically, the Company has found its application of accounting policies to be appropriate, and actual results have not differed materially from those determined using necessary estimates.

FOREIGN CURRENCY TRANSLATION

The financial statements of the Israeli subsidiaries have been prepared using the U.S. dollar as the functional currency. Transactions in foreign currency (primarily in New Israeli Shekels – "NIS") are recorded at the representative exchange rate as of the transaction date, except for activities relating to balance sheet items, which are recorded at the appropriate exchange rate of the corresponding balance sheet item. Monetary assets and liabilities in foreign currency are stated on the basis of the representative rate of exchange at the balance sheet date. Non-monetary assets and liabilities in foreign currency are stated at historical exchange rates. All exchange gains and losses from remeasurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as they arise.

CASH AND CASH EQUIVALENTS

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

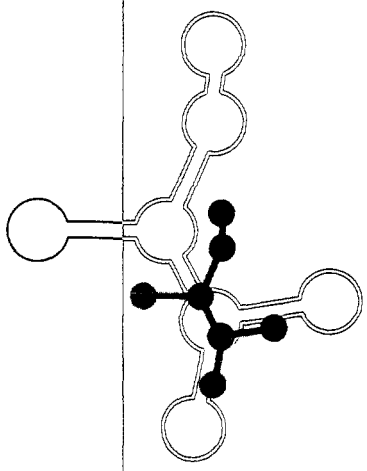
INVESTMENT SECURITIES

Investment securities at December 31, 2004 and 2003 consist of short-term government, auction notes and corporate debt securities. The Company classifies its short-term debt securities as held-to-maturity, with the exception of auction notes securities, which are classified as available-for-sale. Held-to-maturity securities are those securities in which the Company has the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts.

A decline in the market value of any held-to-maturity security below cost, that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Dividend and interest income are recognized when earned.

NOTE AND ACCRUED INTEREST RECEIVABLE

Note and accrued interest receivable are recorded at contractual value plus accrued interest. Note and accrued interest receivable related to a short-term promissory note purchased from ACCESS Oncology, a related party and, subsequently, a subsidiary of the Company. Upon the completion of the merger, the promissory notes were assumed by the Company.



PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are stated at historical cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets:

	Estimated useful life (years)
Office furniture and equipment	3-7
Computers, software and related equipment	3

INTANGIBLE ASSETS

The Company expenses patent costs as incurred. Historically, certain acquired patents have been recorded at cost and are being amortized over a four-year period. The Company continually evaluates whether events and circumstances warrant the recognition of a reduction of carrying amounts.

REVENUE RECOGNITION

Revenues consist of clinical trial management and site recruitment services. Revenues generated from providing clinical trial management and site recruitment services are recognized at the time such services are provided. Deferred revenue is incurred when the Company receives a deposit or prepayment for services to be performed at a later date. Management fees accumulated during the development stage arose from provision of management services to a related company and were recognized ratably over the period for which the services were provided.

COST OF SERVICES

Cost of services consist of all costs specifically associated with client programs such as salary, benefits paid to personnel, payments to third-party vendors and systems and other support facilities associated with delivering services to the Company's clients. Cost of services are recognized at the time such services are performed.

RESEARCH AND DEVELOPMENT COSTS

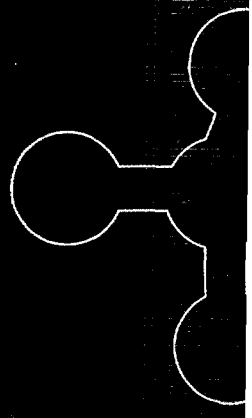
Research and development costs are expensed as incurred.

INCOME TAXES

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary and permanent differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. If the likelihood of realizing the deferred tax assets or liability is less than "more likely than not," a valuation allowance is then created.

STOCK - BASED COMPENSATION (IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

The Company applies the intrinsic value-based method of accounting prescribed by the Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and related interpretations, including FASB Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation, an Interpretation of APB Opinion No. 25," to account for its fixed-plan stock options for employees and directors. Under this method, compensation expense is recorded on the date of grant only if the current market price of



the underlying stock exceeded the exercise price. Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123") is applied to stock options and warrants granted to persons other than employees and directors. The Company has adopted the disclosure requirements of SFAS No. 123 and SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure," ("SFAS No. 148") for awards to its directors and employees.

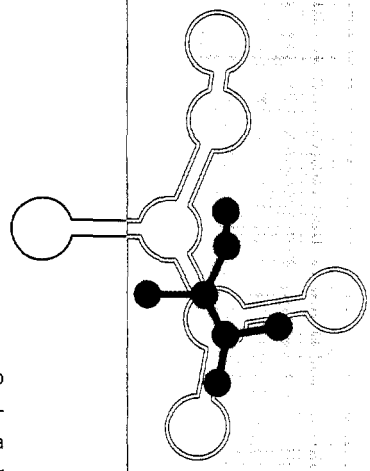
The following is a pro forma unaudited presentation of reported net loss and net loss per share, calculated to show adjusted values had the compensation expenses for stock options granted under the Company's stock option plans been determined based on fair value at the grant dates consistent with the method of SFAS No. 123:

	For the year ended December 31			Amounts accumulated during the development stage
(in thousands, except per share amounts)	**2004**	**2003**	**2002**	
Net loss, as reported	**$ (32,943)**	$ (9,108)	$ (11,783)	$ (87,553)
Add: Stock-based compensation expense to employees and directors determined under the intrinsic value-based method, as included in reported net loss	**687**	80	104	9,707
Deduct: Stock-based compensation expense to employees and directors determined under fair value based method	**(3,770)**	(1,286)	(1,282)	(16,419)
Pro forma net loss	**$ (36,026)**	$ (10,314)	$ (12,961)	$ (94,265)
Basic and diluted loss per common share:				
As reported	**$ (1.10)**	$ (0.43)	$ (0.59)	$ (5.46)
Pro forma	**$ (1.20)**	$ (0.48)	$ (0.65)	$ (5.88)

The value of these options has been estimated using the Black-Scholes model. The weighted average fair market value of options granted during the year ended December 31, 2004, as of the date of the grant, was $4.38. The assumptions used in the calculation of the fair value of options granted during the year ended December 31, 2004 were a weighted average expected term of 4.8 years, a weighted average expected volatility rate of 84.24% and a weighted average risk-free interest rate of 2.85%. The weighted average fair market value of options granted during the year ended December 31, 2003, as of the date of the grant, was $0.93. The assumptions used in the calculation of the fair value of options granted during the year ended December 31, 2003 were a weighted average expected term of 4.0 years, a weighted average expected volatility rate of 82.74% and a weighted average risk-free interest rate of 2.39%. The assumptions used in the calculation of the fair value for compensation expense during the year ended December 31, 2002 were a weighted average expected life of 1-4 years, an expected volatility rate of 78.65-83.09% and a risk-free interest rate of 1.5%-3.5%.

NET LOSS PER SHARE

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon exercise of stock options and warrants, as their inclusion would be anti-dilutive. The options and warrants exercisable as of December 31, 2004, 2003 and 2002, which are not included in the computation of net loss per share amounts, were 3,807,576, 3,510,230, and 4,466,612, respectively.



IMPAIRMENT OF LONG-LIVED ASSETS AND LONG-LIVED ASSETS TO BE DISPOSED OF

The Company accounts for impairment using the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"). This Statement requires that long-lived assets subject to amortization be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated.

BUSINESS ACQUISITIONS

The Company accounts for acquired businesses using the purchase method of accounting which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. Our consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition and are not retroactively restated. The cost to acquire a business, including transaction costs, is allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Any excess of the net assets acquired over the purchase price represents negative goodwill.

The acquisition of ACCESS Oncology (see Note 6 – ACCESS Oncology Acquisition) resulted in negative goodwill. Since the negative goodwill was a result of not recognizing contingent consideration (i.e., the contingent equity rights), the lesser of the negative goodwill and the maximum value of the contingent equity rights at the date of the acquisition was recorded as if it were a liability, thereby eliminating the negative goodwill.

CONCENTRATIONS OF CREDIT RISK

The Company does not have significant off-balance-sheet risk or credit risk concentrations. The Company maintains its cash and cash equivalents and short-term investments with multiple financial institutions and invests in investment-grade securities with maturities of less than twenty-four months.

RECENTLY ISSUED ACCOUNTING STANDARDS

In December 2004, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 123R, Share-Based Payment. SFAS 123R replaces SFAS 123, Stock-Based Compensation, issued in 1995. SFAS 123R requires that the fair value of the grant of employee stock options be reported as an expense. Historically, the Company has disclosed in its footnotes the pro forma expense effect of stock options granted under the Company's stock option plans in Note 1, Organization and Summary of Significant Accounting Policies: Stock-Based Compensation. The Company plans to adopt SFAS 123R when required in the third quarter of 2005. The estimated impact of adopting SFAS 123R will have a material impact on the Company's consolidated financial statements.

NOTE 2 – CASH AND CASH EQUIVALENTS

(in thousands)	December 31, 2004	December 31, 2003
Money market funds	$ 12,904	$ 17,069
Securities (original maturity less than 90 days)	1,249	—
Checking and bank deposits	15,546	4,603
Total	$ 29,699	$ 21,672

NOTE 3 - INVESTMENT SECURITIES

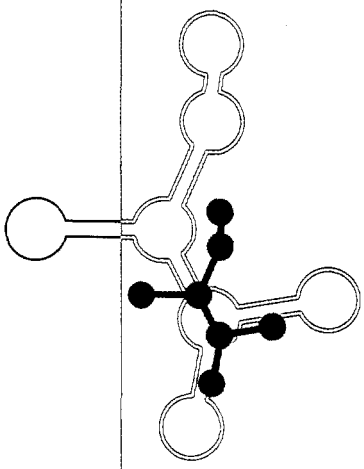
The following tables summarize the Company's investment securities at December 31, 2004 and December 31, 2003 (regarding assumptions used for estimated fair value, see "Note 8 – Fair Value of Financial Instruments."):

	December 31, 2004			
(in thousands)	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (mature between February and September 2005)	$ 12,911	$ —	$ (66)	$ 12,845
Auction notes **	5,025	—	—	5,025
US corporate debt securities (mature between January and April 2005)	2,099	—*	(2)	2,097
	$ 20,035	$ —*	$ (68)	$ 19,967

	December 31, 2003			
(in thousands)	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (mature between January and August 2004)	$ 5,535	$ 3	$ —*	$ 5,538
US corporate debt securities (mature between January and June 2004)	4,096	—	(3)	4,093
	$ 9,631	$ 3	$ (3)	$ 9,631

* Amount less than one thousand dollars.

**Amortized cost approximates fair value. Unrealized gains and losses are not material.



NOTE 4 - PROPERTY, PLANT AND EQUIPMENT

(in thousands)	December 31, 2004	December 31, 2003
Office furniture and equipment	**$ 104**	$ 11
Computers, software and related equipment	**158**	63
	262	74
Accumulated depreciation and amortization	**(117)**	(50)
Net book value	**$ 145**	$ 24

Depreciation expense for the years ended December 31, 2004, 2003 and 2002 was approximately $67,000, $841,000 and $893,000, respectively. The following table summarizes depreciation expense for the years ended December 31, 2004, 2003 and 2002.

	For the year ended December 31		
(in thousands)	2004	2003	2002
Depreciation expense:			
Cost of services	**$ 7**	$ —	$ —
Research and development	**44**	188	605
General and administrative	**16**	653	288
Total	**$ 67**	$ 841	$ 893

During 2003, as part of the Company's decision to vacate the Jerusalem facility, the Company reevaluated and significantly shortened the useful life of the leasehold improvements associated with its administrative facilities, resulting in accelerated depreciation of approximately $561,000 for the year ended December 31, 2003. Following the accelerated depreciation, the leasehold improvements were completely written off in 2003. In addition, as part of the 2003 restructuring, the Company recorded a non-cash impairment charge of approximately $1,695,000 for the year ended December 31, 2003, of which approximately $1,571,000 was included in research and development expenses and approximately $124,000 was included in general and administrative expenses.

NOTE 5 - OTHER ASSETS

(in thousands)	December 31, 2004	December 31 2003
Patents and other intangible assets	**$ 352**	$ 1,187
Long-term deposits	**59**	—
Deferred registration fees	**26**	—
	437	1,187
Impairment loss	**—**	(787)
Accumulated patent amortization	**(220)**	(180)
	$ 217	$ 220

Amortization expense for the years ended December 31, 2004, 2003 and 2002 was approximately $88,000, $99,000 and $59,000, respectively. The Company expects amortization expense for the years ended December 31, 2005, 2006 and 2007 to be approximately $88,000, $44,000 and $0, respectively.

As part of the 2003 restructuring, the Company recorded a non-cash impairment charge of approximately $787,000 for the year ended December 31, 2003, all of which was included in research and development expenses.

NOTE 6 – ACCESS ONCOLOGY ACQUISITION

On February 5, 2004, the Company acquired ACCESS Oncology, a related party, for a purchase price of approximately $19,502,000, which included the Company's assumption of certain liabilities of ACCESS Oncology equal to approximately $8,723,000, the issuance of shares of the Company's common stock valued at approximately $6,325,000, contingent equity rights valued at approximately $4,004,000 and transaction costs of approximately $450,000.

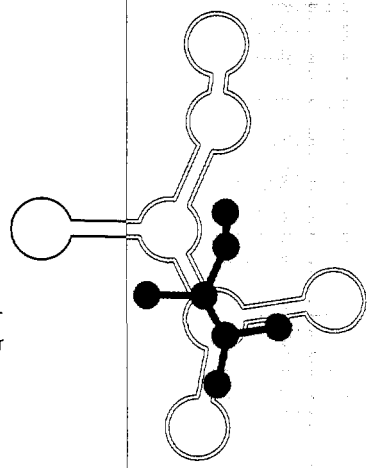
At the effective time of the merger, each share of ACCESS Oncology common stock, including shares issuable upon the exercise of options exercised before March 1, 2004, and upon the exercise of outstanding warrants, was converted into the right to share in the contingent equity rights pro rata with such other holders of ACCESS Oncology common stock. Pursuant to the merger agreement, 623,145 shares of the Company's common stock valued at approximately $6,325,000 have been issued to the preferred stockholders of ACCESS Oncology. An additional 4,433 shares of the Company's common stock are issuable to those preferred stockholders of ACCESS Oncology who have yet to provide the necessary documentation to receive shares of the Company's common stock.

The contingent equity rights will be paid upon the achievement of the following milestones:

- 500,000 shares of the Company's common stock upon enrollment of the first patient in a Keryx-sponsored Phase III (or other pivotal) clinical trial for any of the acquired ACCESS Oncology drug candidates;
- 750,000 shares of the Company's common stock upon the first new drug application acceptance by the Food and Drug Administration, or FDA, for any of the acquired ACCESS Oncology drug candidates;
- 1,750,000 shares of the Company's common stock upon the first FDA approval of any of the acquired ACCESS Oncology drug candidates; and
- 372,422 shares of the Company's common stock following the first 12-month period that sales of all of the acquired ACCESS Oncology drug candidates combined exceeds $100 million.

In no event will the Company issue more than 4,000,000 shares of its common stock pursuant to the merger agreement. These 4,000,000 shares include 627,578 shares issued or issuable to date and any contingent shares as described above. Accordingly, the amount of the Company's common stock deliverable to the ACCESS Oncology stockholders as milestone consideration will be no more than 3,372,422 shares of the Company's common stock, which is the portion of the common stock deliverable as contingent consideration pursuant to the merger agreement. The Company's stockholders approved the issuance of shares of its common stock payable as contingent milestone consideration at the 2004 annual meeting of stockholders, which took place on June 10, 2004.

The ACCESS Oncology acquisition has been accounted for as a purchase by the Company under U.S. generally accepted accounting principles. Under the purchase method of accounting, the assets and liabilities assumed from ACCESS Oncology are recorded at the date of acquisition at their respective fair values. The consolidated



financial statements and reported results of operations of the Company issued after completion of the acquisition will reflect these values but will not be restated retroactively to reflect the historical financial position or results of operations of ACCESS Oncology.

The following represents the purchase price for ACCESS Oncology:

(in thousands, except share and per share amounts)		
Assumed liabilities		$ 8,723
Number of shares of Keryx common stock issued	623,145	
Multiplied by Keryx's volume-adjusted weighted average closing price per share measured over the last seven trading days immediately preceding the closing	$ 10.15	6,325
Contingent equity rights		4,004
Other transaction costs		450
Total purchase price		$ 19,502

The excess of the net assets acquired over the purchase price represented negative goodwill of approximately $4,004,000. Since the negative goodwill is a result of not recognizing contingent consideration (i.e., the contingent equity rights), the lesser of the negative goodwill ($4,004,000) and the maximum value of the contingent equity rights at the date of the acquisition ($34,275,000) has been recorded as a liability, thereby eliminating the negative goodwill. The value of the contingent equity rights of $34,275,000 was based on the volume-adjusted weighted average closing price per share of the Company's common stock measured over the last seven trading days immediately preceding the closing of the acquisition ($10.15 per share) multiplied by 3,376,855 shares, which consist of the sum of the unissued amount of the Company's common stock deliverable to the ACCESS Oncology stockholders as milestone consideration (3,372,422 shares) and to those preferred stockholders of ACCESS Oncology who have yet to provide the necessary documentation to receive shares of the Company's common stock (4,433 shares).

The purchase price allocation, which is considered final, is based on an estimate of the fair value of net assets acquired.

(in thousands)	
Allocation of purchase price:	
Net assets acquired	$ 725
Adjusted for write-off of existing intangible assets	23
Net tangible assets acquired	702
Acquired in-process research and development charge	18,800
Purchase price	$ 19,502

As required by FASB Interpretation No. 4, "Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method" ("FIN 4"), the Company recorded a charge in 2004 of $18,800,000 for the portion of the purchase price allocated to acquired in-process research and development.

A project-by-project valuation using the guidance in SFAS No. 141, "Business Combinations" and the AICPA Practice Aid "Assets Acquired in a Business Combination to Be Used In Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries" was performed with the assistance of independent valuation specialists to determine the fair value of research and development projects of ACCESS Oncology which were in-process, but not yet completed.

The fair value was determined using the income approach on a project-by-project basis. This method starts with a forecast of the expected future net cash flows. These cash flows are then adjusted to present value by apply-

ing an appropriate discount rate that reflects the project's stage of completion and other risk factors. These other risk factors can include the nature of the product, the scientific data associated with the technology, the current patent situation and market competition.

The forecast of future cash flows required the following assumptions to be made:

revenue that is likely to result from specific in-process research and development projects, including estimated patient populations, estimated selling prices, estimated market penetration and estimated market share and year-over-year growth rates over the product life cycles;

- cost of sales related to the potential products using industry data or other sources of market data;
- sales and marketing expense using industry data or other sources of market data;
- general and administrative expenses; and
- research and development expenses.

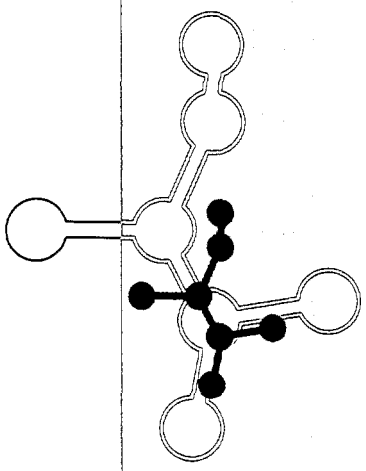
The valuations are based on information that is available as of the acquisition date and the expectations and assumptions that have been deemed reasonable by our management. No assurance can be given, however, that the underlying assumptions or events associated with such assets will occur as projected. For these reasons, among others, the actual results may vary from the projected results.

The following unaudited pro forma financial information presents the combined results of operations of the Company and ACCESS Oncology as if the acquisition had occurred as of the beginning of the periods presented. The unaudited pro forma financial information is not necessarily indicative of what the Company's consolidated results of operations actually would have been had it completed the acquisition at the dates indicated. In addition, the unaudited pro forma financial information does not purport to project the future results of operations of the combined company.

(in thousands, except per share amounts)	**2004**	**2003**
Revenue	**$ 911**	$ 786
Net loss	**$ (14,086)**	$ (12,113)
Basic and diluted loss per common share	**$ (0.47)**	$ (0.55)

The unaudited pro forma financial information above reflects the elimination of balances and transactions between the Company and ACCESS Oncology, which upon completion of the merger would be considered intercompany balances and transactions. The entries include the elimination of certain interest income and expense and the elimination of the reimbursement of salaries and related facility costs of two employees of ACCESS Oncology, both of which net to zero.

The unaudited pro forma financial information above excludes the non-recurring, non-cash charge of $18,800,000 related to acquired in-process research and development in the year ended December 31, 2004.



NOTE 7 - STOCKHOLDERS' EQUITY

PREFERRED STOCK

The Company's amended and restated certificate of incorporation allows it to issue up to 5,000,000 shares of preferred stock, $0.001 par value, with rights senior to those of the common stock.

COMMON STOCK

In June 2004, the Company's stockholders approved an amendment to the Company's amended and restated certificate of incorporation increasing by 20 million the number of shares of authorized common stock to 60 million shares.

In June 2004, the Company's stockholders approved the delisting of the Company's common stock from the Alternative Investment Market of the London Stock Exchange, which became effective on August 10, 2004.

During 2004, the Company issued 623,145 shares of its common stock, valued at approximately $6,325,000 million, to the preferred stockholders of ACCESS Oncology, in connection with the Company's merger with ACCESS Oncology, which closed on February 5, 2004. An additional 4,433 shares of the Company's common stock are issuable to those preferred stockholders of ACCESS Oncology who have yet to provide the necessary documentation to receive shares of the Company's common stock. In addition, up to 3,372,422 shares of the Company's common stock are deliverable to the ACCESS Oncology stockholders as contingent milestone consideration pursuant to the merger agreement. The Company's stockholders approved the issuance of shares of its common stock payable as contingent milestone consideration in June 2004 (see Note 6 above).

On February 17, 2004, the Company completed a private placement of approximately 3.2 million shares of its common stock to institutional investors at $10.00 per share. Total net proceeds of this private placement were approximately $31.7 million, net of offering expenses of approximately $0.3 million. In connection with this private placement, the Company filed a Registration Statement on Form S-3 (File No. 333-113654) on March 16, 2004, and Amendment No. 1 to the Registration Statement on Form S-3/A on April 1, 2004, which was declared effective by the SEC on May 3, 2004.

On November 20, 2003, the Company completed a private placement of approximately 3.5 million shares of its common stock together with warrants for the purchase of an aggregate of 705,883 shares of its common stock at an exercise price of $6.00 per share. Total proceeds of this private placement were approximately $14.1 million, net of offering expenses of approximately $0.9 million. In addition, the Company issued to the placement agent a warrant to purchase 50,000 shares of its common stock at an exercise price of $6.00. In connection with the private placement, the Company filed a Registration Statement of Form S-3 (File No. 333-111133) on December 12, 2003, and Amendment No. 1 to the Registration Statement on Form S-3/A on December 19, 2003, which was declared effective by the SEC on December 19, 2003.

The Company completed its initial public offering of 4.6 million shares of its common stock at $10.00 per share pursuant to a Registration Statement on Form S-1 (File No. 333-37402), which was effective on July 28, 2000. Additionally, the underwriters exercised their over-allotment option and purchased an additional 600,000 shares of the Company's common stock, at $10.00 per share, on August 30, 2000. Total proceeds of this offering, including the exercise of the over-allotment option, were approximately $46.3 million, net of underwriting fees and offering expenses of approximately $5.7 million.

The Company repurchased 9,800 shares of its common stock at an aggregate cost of approximately $12,000 and 46,300 shares of its common stock at an aggregate cost of approximately $77,000 during the years ended December 31, 2003 and 2002, respectively, pursuant to the stock repurchase program approved by the Company's Board of Directors in November 2002. At December 31, 2003, the stock repurchase program ended.

During 2002, the Company issued a total of 48,491 unregistered shares of its common stock with a weighted average fair value at grant date of approximately, $359,000, or $7.40 per share, to third parties.

STOCK OPTION PLANS

The Company has in effect the following stock option plans. Options granted typically vest over a three to four year period.

The Company has in effect the following stock option plans.

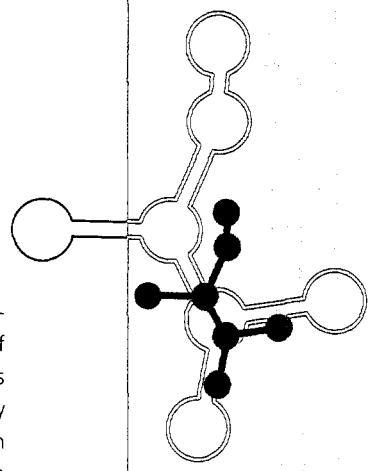
a. The "1999 Stock Option Plan" adopted in November 1999, pursuant to which the Company's board of directors could grant stock-based awards to directors, consultants and employees. The plan authorizes grants to purchase up to 4,230,000 shares of authorized but unissued common stock. The plan limits the term of each option, to a term of no more than twenty-five (25) years from the date of the grant, unless authorized by the board. The plan is administered by the board of directors or a committee appointed by the Board, which has the authority, in its discretion, to determine the terms and conditions of any option granted to a Company service provider, including the vesting schedule.

b. The "2000 Stock Option Plan" adopted in June 2000, pursuant to which the compensation committee of the Company's board of directors could grant stock-based awards to directors, consultants and employees. The 2000 plan authorizes grants to purchase up to 4,455,000 shares of authorized but unissued common stock. The plan limits the term of each option, to a term of no more than 10 years from the date of the grant, unless authorized by the board.

c. The "Non-Plan" adopted in February 2000, pursuant to which the Company's board of directors granted options, which are not part of any plan, to non-employee directors of the Company to purchase up to 240,000 shares of authorized but unissued common stock. The options issued by the board of directors pursuant to the Non-Plan have a life of 10 years from the date of their grant.

d. The "2002 CEO Incentive Stock Option Plan" adopted in December 2002, pursuant to which the Company's board of directors granted an option to the newly-appointed Chief Executive Officer of the Company to purchase up to 2,002,657 shares of authorized but unissued common stock. The option has a term of no more than 10 years plus one day from the date of the grant, unless otherwise authorized by the Company's board of directors. The option granted to the newly appointed Chief Executive Officer was part of a total grant of options issued pursuant to the 1999 Stock Option Plan, the 2000 Stock Option Plan and the 2002 CEO Incentive Stock Option Plan, to purchase a total of 4,050,000 shares of the Company's common stock. Of these options, one-third (or 1,350,000) vest over a three-year period and two-thirds (or 2,700,000) vest upon the earlier of the achievement of certain performance-based milestones or December 23, 2012. In addition, in the event of a merger, acquisition or other change of control or in the event that the Company terminates the Chief Executive Officer's employment, either without cause or as a result of his death or disability, or he terminates his employment for good reason, the exercisability of any of the options described in this paragraph that are unexercisable at the time of such event or termination shall accelerate and the time period during which he shall be allowed to exercise such options shall be extended to the shorter of two years from the date of the termination of his employment or December 24, 2012. Additionally, the Company's board of directors shall have the discretion to accelerate all or a portion of these options at any time.

e. The "2004 President Incentive Stock Option Plan" adopted in February 2004, pursuant to which the Company's board of directors granted an option to the newly-appointed President of the Company to purchase up to 1,000,000 shares of authorized but unissued common stock. The option has a term of no more than 10 years plus one day from the date of the grant, unless otherwise authorized by the Company's board of directors. The option granted to the newly appointed President was made pursuant to an employment agreement following the acquisition of ACCESS Oncology, Inc. in February 2004. Of these options, 166,667



vest over a three-year period and 833,333 vest upon the earlier of the achievement of certain performance-based milestones or January 2, 2014. In addition, in the event of a merger, acquisition or other change of control or in the event that the Company terminates the President's employment, either without cause or as a result of his death or disability, or he terminates his employment for good reason, the exercisability of any of the options described in this paragraph that are unexercisable at the time of such event or termination shall accelerate and the time period during which he shall be allowed to exercise such options shall be extended to the shorter of two years from the date of the termination of his employment or January 2, 2014. Additionally, the Company's board of directors shall have the discretion to accelerate all or a portion of these options at any time.

f. The "2004 Long-Term Incentive Plan" adopted in June 2004, pursuant to which the compensation committee of the Company's board of directors could grant stock-based awards to directors, consultants and employees. The 2004 plan authorizes grants to purchase up to 4,000,000 shares of authorized but unissued common stock. The plan limits the term of each option, to a term of no more than 10 years from the date of their grant.

The following table summarizes stock options authorized by the Company as of December 31, 2004.

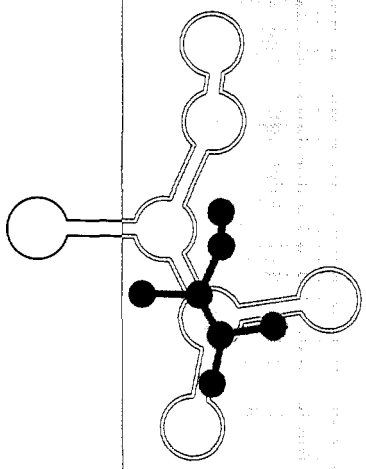
Stock option plan	Exercise price per share	Authorized	Outstanding	Exercised	Exercisable	Available for grant
1999 Stock Option Plan	$ 0.10 - 1.30	4,230,000	855,595	3,329,405	681,924	—
2000 Stock Option Plan	1.07 - 19.00	4,455,000	2,963,869	600,809	1,662,658	890,322
Non Plan	0.33	240,000	195,000	22,500	195,000	22,500
2002 CEO Incentive Stock Option Plan	1.30	2,002,657	2,002,657	—	1,001,329	—
2004 President Incentive Plan	4.59	1,000,000	1,000,000	—	166,667	—
2004 Long-Term Incentive Plan	1.92 - 12.35	4,000,000	657,500	—	100,000	3,342,500
Totals		15,927,657	7,674,621	3,952,714	3,807,576	4,255,322

A summary of the status of the Company's stock options as of December 31, 2004, 2003, 2002, and changes during the years then ended is presented in the tables below.

	Outstanding stock options		
	Shares available	Number of shares	Weighted-average exercise price
Balance, December 31, 2001	3,562,904	5,186,096	$ 1.76
Authorized	2,002,657		
Granted	(4,398,884)	4,398,884	1.40
Exercised	—	(18,000)	0.10
Canceled	221,953	(221,953)	5.15
Balance, December 31, 2002	1,388,630	9,345,027	1.51
Restatement	(45,000)		
Authorized	—		
Granted	(1,005,000)	1,005,000	1.35
Exercised	—	(1,574,276)	0.12
Canceled	771,442	(771,442)	5.10
Balance, December 31, 2003	1,110,072	8,004,309	1.42
Authorized	5,000,000		
Granted	(1,870,000)	1,870,000	6.42
Exercised	—	(2,184,438)	1.35
Canceled	15,250	(15,250)	8.15
Balance, December 31, 2004	4,255,322	7,674,621	2.64
Exercisable at December 31, 2002		4,466,612	$ 1.12
Exercisable at December 31, 2003		3,510,230	$ 1.54
Exercisable at December 31, 2004		3,807,576	$ 1.75

	For the year ended December 31,		
	2004	2003	2002
Weighted-average fair value of options granted during the period at an exercise price equal to market price at issue date	**$ 4.37**	$ 0.83	$ 1.02
Weighted-average exercise price of options granted during the period at an exercise price equal to market price at issue date	**$ 6.42**	$ 1.35	$ 1.38
Weighted-average fair value of options granted during the period at an exercise price greater than market price at issue date	**N/A**	$ 2.46	$ 1.48
Weighted-average exercise price of options granted during the period at an exercise price greater than market price at issue date	**N/A**	$ 1.38	$ 1.97

During 2004, the compensation committee of the Company's board of directors granted options to purchase 1,870,000 shares of the Company's common stock to the Company's employees, directors and consultants (including an option to purchase 1,000,000 shares granted to I. Craig Henderson, M.D., the Company's President, who joined the Company pursuant to the acquisition of ACCESS Oncology in February 2004). In addition, options to purchase 150,000 shares of our common stock that were contingently granted to two non-employee directors in June 2003 were issued under the 2004 Long-Term Incentive Plan which was approved, on June 10, 2004, at the 2004 annual meeting of stockholders.



The following table summarizes information about stock options outstanding at December 31, 2004:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Number exercisable	Weighted-average exercise price
$ 0.10	482,752	14.4	$ 0.10	482,752	$ 0.10
0.11 - 0.50	195,000	5.0	0.33	195,000	0.33
0.51 - 3.00	4,885,151	8.1	1.31	2,679,627	1.32
3.01 - 5.75	1,468,218	8.8	4.62	304,885	4.73
5.76 - 10.00	164,000	8.6	8.52	50,500	8.70
10.01 - 19.00	479,500	9.0	11.62	94,813	11.89
	7,674,621			3,807,576	

At December 31, 2004, 3,670,077 options issued to directors and employees and 282,637 options issued to consultants have been exercised. The terms of the outstanding options at December 31, 2004 are as follows:

TO DIRECTORS AND EMPLOYEES

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Number exercisable	Weighted-average exercise price
$ 0.10	472,752	14.3	$ 0.10	472,752	$ 0.10
0.11 - 0.50	195,000	5.0	0.33	195,000	0.33
0.51 - 3.00	4,829,651	8.1	1.31	2,637,847	1.32
3.01 - 5.75	1,403,218	8.8	4.62	298,025	4.71
5.76 - 10.00	128,000	8.5	8.81	37,000	8.80
10.01 - 19.00	367,000	8.8	11.87	92,000	11.92
	7,395,621			3,732,624	

As of December 31, 2004, 3,733,333 options issued to directors and employees are milestone-based.

TO CONSULTANTS

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Number exercisable	Weighted-average exercise price
$ 0.10	10,000	19.5	$ 0.10	10,000	$ 0.10
0.11 - 0.50	—	N/A	N/A	—	N/A
0.51 - 3.00	55,500	8.5	1.57	41,780	1.77
3.01 - 5.75	65,000	9.0	4.59	6,860	5.31
5.76 - 10.00	36,000	8.9	7.50	13,500	8.43
10.01 - 19.00	112,500	9.5	10.80	2,812	10.77
	279,000			74,952	

As of December 31, 2004, 75,000 options issued to consultants are milestone-based.

The Company applies APB Opinion No. 25 in accounting for its options granted to directors and employees. For the years ended December 31, 2004, 2003 and 2002, the Company has recorded non-cash compensation expense of approximately $667,000, $65,000 and $105,000, respectively.

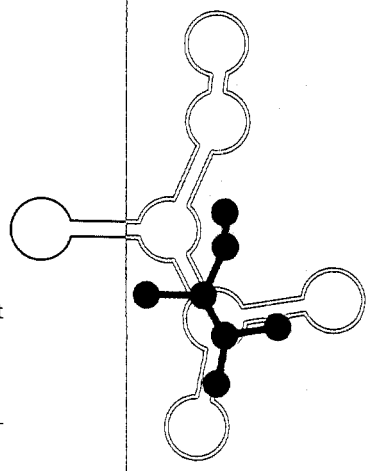
The Company applies EITF 96-18 "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," in accounting for its options granted to consultants. For the years ended December 31, 2004, 2003 and 2002, the Company recorded non-cash compensation expense of approximately $833,000, $163,000 and a credit of $132,000, respectively. Unvested options are revalued at every reporting period and amortized over the vesting period in order to determine the compensation expense. The value of these options has been estimated using the Black-Scholes model under the assumptions stated above (see Note 1).

WARRANTS

A summary of the status of the Company's warrants issued as of December 31, 2004, 2003, 2002, and changes during the years then ended is presented in the tables below.

	Warrants	Weighted-average exercise price
Balance, December 31, 2001	544,801	$ 0.42
Issued	500,000	6.19
Exercised	—	—
Canceled	—	—
Balance, December 31, 2002	1,044,801	3.18
Issued	755,883	6.00
Exercised	—	—
Canceled	(558,307)	5.75
Balance, December 31, 2003	1,242,377	3.74
Issued	—	—
Exercised	(348,824)	6.00
Canceled	(375,000)	0.01
Balance, December 31, 2004	518,553	$ 4.86

	For the year ended December 31,		
	2004	**2003**	**2002**
Weighted-average fair value of warrants granted during the period at an exercise price equal to market price at issue date	**NA**	NA	$ 2.33
Weighted-average exercise price of warrants granted during the period at an exercise price equal to market price at issue date	**NA**	NA	$ 6.19
Weighted-average fair value of warrants granted during the period at an exercise price greater than market price at issue date	**NA**	$ 3.45	NA
Weighted-average exercise price of warrants granted during the period at an exercise price greater than market price at issue date	**NA**	$ 6.00	NA



As of December 31, 2004, 596,246 warrants have been exercised and no warrants have been cancelled as part of cashless exercises. The terms of outstanding warrants as of December 31, 2004 are as follows:

	Warrants outstanding			Warrants exercisable	
Range of exercise prices	Number outstanding	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Number exercisable	Weighted-average exercise price
$ 0.0067 - 1.94	111,494	4.2	$ 0.68	111,494	$ 0.68
6.00	407,059	4.0	6.00	407,059	6.00
	518,553	4.1	$ 4.86	518,553	$ 4.86

As part of the private placement completed on November 20, 2003, the Company issued warrants for the purchase of an aggregate of 705,883 shares of its common stock at an exercise price of $6.00. In addition, the Company issued to the placement agent in the transaction a warrant to purchase up to 50,000 shares of its common stock at an exercise price of $6.00. At the time of grant, the fair market value of each warrant was $3.46 per share. The warrants have a term of exercise of five years. As of December 31, 2004, 348,824 warrants have been exercised by the holders.

The Company applies EITF 96-18 in accounting for its warrants granted to non-employees and non-directors. For the years ended December 31, 2004, 2003 and 2002, the Company recorded non-cash compensation expense of $0, a credit of $527,000 and a credit of $1,358,000, respectively. Unvested warrants are revalued at every reporting period and amortized over the vesting period in order to determine the compensation expense.

The value of these warrants has been estimated using the Black-Scholes model. No warrants were issued in 2004. The assumptions used in the calculation of the fair value for compensation expense during the year ended December 31, 2003 were a weighted average expected life of 5 years, an expected volatility rate of 84.80% and a risk-free interest rate of 3.2%. The assumptions used in the calculation of the fair value for compensation expense during the year ended December 31, 2002 were a weighted average expected life of 0-3 years, an expected volatility rate of 78.65-83.09% and a risk-free interest rate of 1.5%-3.5%.

NOTE 8 - FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company's financial instruments at December 31, 2004 and 2003 consisted of cash and cash equivalents, investment securities, note and accrued interest receivable, accrued interest receivable, other receivables, and accounts payable and accrued expenses.

The carrying amounts of all the financial instruments noted above, except for investment securities, approximate fair value for all years presented due to the relatively short maturity of these instruments. The carrying amount for investment securities (held to maturity) are based on the amortized cost for these investments at the reporting date. The difference between the carrying value and fair value of investment securities held-to-maturity is set forth in Note 3 above. The carrying amount of available-for-sale investment securities (auction notes) is based on cost, which approximates fair value due to the rate re-pricing mechanism.

NOTE 9 – INCOME TAXES

As of December 31, 2004, the Company has U.S. net operating loss carryforwards of approximately $65.3 million which expire from 2019 through 2024. In addition, as of the date of the acquisition, ACCESS Oncology had U.S. net operating loss carryforwards of $14.9 million that start to expire in December 2019. Deferred tax assets of Partec were lost upon assumption of operations by the Company (see Note 1 – Organization and Summary of Significant Accounting Policies).

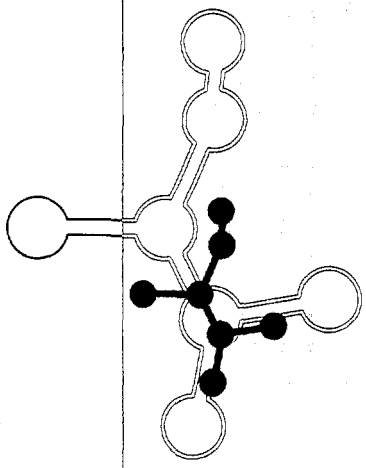
The Company has established a valuation allowance against its net deferred tax assets due to the Company's pre-tax losses and the resulting likelihood that the deferred tax asset is not realizable. The valuation allowance for deferred tax assets was $38.9 million and $19.8 million as of December 31, 2004 and 2003, respectively. If the entire deferred tax asset were realized, $7.1 million would be allocated to paid-in-capital related to the tax effect of compensation deductions from the exercise of employee and consultant stock options. Due to the Company's various equity transactions, the utilization of certain tax loss carryforwards is subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision.

In prior periods, the Company's wholly-owned Israeli subsidiaries had generated taxable income in respect of services provided within the group, and therefore, the Company believed in the past that its deferred tax assets relating to the Israeli subsidiaries would be realized. With the cessation of operating activities in Israel during 2003 and the resulting absence of taxable income from the Israeli subsidiaries, the deferred tax asset was written off in 2003.

In September 2001, one of the Company's Israeli subsidiaries received the status of an "Approved Enterprise," a status which grants certain tax benefits in Israel in accordance with the "Law for the Encouragement of Capital Investments, 1959." Since inception, the Company's Israeli subsidiary, which ceased operations in 2003, has received tax benefits in the form of exemptions of approximately $744,000 as a result of our subsidiary's status as an "Approved Enterprise." As part of the restructuring implemented during 2003 (see Note 12 – Restructuring), the Company closed down its Jerusalem laboratory facility. In October 2003, the subsidiary received a letter from the Israeli Ministry of Industry and Trade that its Approved Enterprise status was cancelled as of July 2003 and that past benefits would not need to be repaid. The Israeli tax authorities have yet to confirm this position; however, the Company believes that, based on the letter received from the Ministry of Industry and Trade, it is unlikely that past benefits will need to be repaid, and therefore, the Company has not recorded any charge with respect to this potential liability.

The tax expense reported in prior periods primarily related to the subsidiaries in Israel. Income tax expense attributable to income from continuing operations was $1,000, $(27,000) and $51,000, for the years ended December 31, 2004, 2003 and 2002, respectively, and differed from amounts computed by applying the US federal income tax rate of 35% to pretax loss.

	For the year ended December 31,		
(in thousands)	**2004**	**2003**	**2002**
Losses before taxes on income, as reported in the consolidated statements of operations	**$ (32,943)**	$ (9,135)	$ (11,732)
Computed "expected" tax benefit	**(11,530)**	(3,197)	(4,106)
Increase (decrease) in income taxes resulting from:			
Expected benefit from state & local taxes	**(2,853)**	(868)	(1,115)
Change in state and local effective tax rate	**—**	1,601	—
Permanent differences – IPR&D	**6,586**	1	(107)
Effect of foreign operations	**143**	901	(581)
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	**7,654**	1,535	5,960
	$ —	$ (27)	$ 51



The significant components of deferred income tax expense (benefit) attributable to income from continuing operations are as follows:

(in thousands)	For the year ended December 31, 2004	2003	2002
Deferred tax benefit	**$ (19,104)**	$ (1,433)	$ (5,947)
Federal deferred tax benefit relating to the exercise of stock options	**5,926**	—	—
Federal deferred tax benefit relating to ACCESS Oncology	**5,524**	—	—
Increase in the valuation allowance for deferred tax assets	**7,654**	1,535	5,960
	$ —	$ 102	$ 13

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2004 and 2003 are presented below.

(in thousands)	December 31, 2004	December 31, 2003
Deferred tax assets/(liabilities):		
Net operating loss carryforwards	**$ 26,903**	$ 12,083
Net operating loss carryforwards (ACCESS Oncology)	**6,128**	—
Non-cash compensation	**2,281**	4,250
Research and development	**2,748**	3,128
Depreciation and amortization	**538**	372
Accrued compensation	**278**	—
Other temporary differences	**68**	7
Net deferred tax asset, excluding valuation allowance	**38,944**	19,840
Less valuation allowance	**(38,944)**	(19,840)
Net deferred tax assets	**$ —**	$ —

NOTE 10 – INTEREST AND OTHER INCOME, NET

The components of interest and other income, net are as follows:

(in thousands)	For the year ended December 31, 2004	2003	2002
Interest income	**$ 690**	$ 272	$ 582
Interest expense and other bank charges	**(27)**	(25)	(69)
Other income	**107**	—	—
	$ 770	$ 247	$ 513

In 2004, other income consisted of a one-time payment of $107,000 from a related-party service agreement that terminated in 2004.

NOTE 11 - COMMITMENTS AND CONTINGENCIES

RESEARCH & DEVELOPMENT AGREEMENTS

The Company has entered into various research and development agreements (primarily relating to our U.S.-based clinical program for KRX-101) under which it is obligated to make payments of approximately $3,867,000 through December 2006. The following table shows future research and development payment obligations by period as of December 31, 2004.

(in thousands)	2005	2006	After 2006
Research and development agreements	$ 3,235	$ 632	$ —

LEASES

The Company leases its office space under lease agreements that expire through 2010. In September 2004, the Company signed a new lease agreement in the same building for its corporate headquarters in New York City for approximately 11,700 square feet, over a period of 5.5 years, at an average rent of approximately $542,000 per year. The new lease will supersede the Company's current lease, which will expire upon its occupation of the new space.

Total rental expense was approximately $240,000, $614,000 and $511,000 for the years ended December 31, 2004, 2003, and 2002, respectively. The Company is currently evaluating various possibilities of leasing approximately 2,000 square feet of space in the San Francisco, California area, to accommodate the Company's oncology group, which is currently based in San Francisco. The Company recorded a $50,000 facility expense, in the year ended December 31, 2004, for the use of the personal facility of the President of the Company for several Company employees located in San Francisco. This amount is included in accounts payable and accrued liabilities at December 31, 2004.

Future minimum lease commitments as of December 31, 2004 are approximately $3,021,000 through 2010. The following table shows future minimum lease commitments by period as of December 31, 2004.

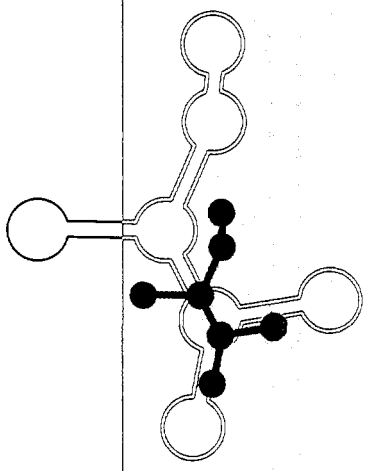
(in thousands)	2005	2006	2007	2008	2009	After 2009
Operating leases	$237	$597	$596	$597	$596	$398

ROYALTY AND CONTINGENT MILESTONE PAYMENTS

The Company has licensed the patent rights to its drug candidates from others. These license agreements require the Company to make contingent milestone payments to certain of its licensors. In addition, under these agreements, the Company must pay royalties on sales of products resulting from licensed technologies.

The Company has undertaken to make contingent milestone payments to certain of its licensors of up to approximately $62.4 million over the life of the licenses, of which approximately $43.3 million will be due upon or following regulatory approval of the drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, the Company remains obligated to pay one licensor $50,000 annually until the license expires. As of December 31, 2004, the Company has recorded a total of $1,200,000 in license and milestone payments in regard to these license agreements.

The Company has also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights if its drug candidates meet development milestones (see Note 6 — Access Oncology Acquisition).



In addition, pursuant to an employment agreement, the Company's Chief Executive Officer is entitled to receive a one-time $2.0 million performance-based cash bonus upon the achievement of a certain working capital or market capitalization milestone event.

NOTE 12 - RESTRUCTURING

In 2003, the Company implemented and completed a strategic reorganization, which the Company sometimes refers to as the "2003 restructuring." As a result of this reorganization the Company ceased all early-stage research and development activities, ceased operations in its Jerusalem lab facility and completed the disposition of its fixed assets in Israel. The 2003 restructuring included a 17-person reduction in the Company's workforce, primarily in Israel. As part of the 2003 restructuring, the Company reevaluated its long-lived assets in accordance with SFAS No. 144 and recorded a non-cash impairment charge of approximately $2,482,000 for the year ended December 31, 2003, of which approximately $2,358,000 was included in research and development expenses and approximately $124,000 was included in general and administrative expenses. The impairment charge included a write-off of approximately $1,695,000 in fixed assets and approximately $787,000 in intangible assets. In addition, with the Company's decision to vacate the Jerusalem facility, the Company reevaluated and significantly shortened the useful life of the leasehold improvements associated with its administrative facilities, resulting in accelerated depreciation of approximately $561,000 for the year ended December 31, 2003. In addition, upon vacating the facility in Jerusalem, the landlord of that facility claimed a bank guarantee in the amount of approximately $222,000 that was previously provided as security in connection with the lease agreement. At December 31, 2004 and 2003, respectively, there were no liabilities associated with the 2003 restructuring accrued for on the Company's balance sheet.

During 2002, the Company implemented a strategic reorganization, which was designed to substantially reduce early stage research expenditures, which the Company sometimes refers to as the "2002 restructuring." The 2002 restructuring included a 46-person reduction in the Company's workforce, primarily in Israel. As part of the restructuring, the Company took a charge in 2002 of approximately $228,000, relating to severance not accrued as part of its ongoing accrual made for employee severance benefits throughout the employment term in accordance with Israeli law, approximately $79,000 of which was included in research and development expenses and approximately $149,000 of which was included in general and administrative expenses. As of December 31, 2003, approximately $82,000 in severance obligations related to the 2002 restructuring was included in accrued compensation and related liabilities and was subsequently paid during the first quarter of 2004. At December 31, 2004, there were no liabilities associated with the 2002 restructuring accrued for on the Company's balance sheet. The following table summarizes the activity with respect the Company's liability in respect of employee severance obligations as associated with the Company's 2002 restructuring.

(in thousands)	Balance at December 31, 2003	Additional accrual	Severance paid	Balance at December 31, 2004
Liability in respect of employee severance obligations	$ 82	$ —	$ (82)	$ —

The following table summarizes restructuring expenses that were incurred by the Company in 2003 and 2002 that were not part of the Company's ongoing accrual for employee severance benefits made throughout the employment term in accordance with Israeli law. No restructuring expenses were incurred in 2004.

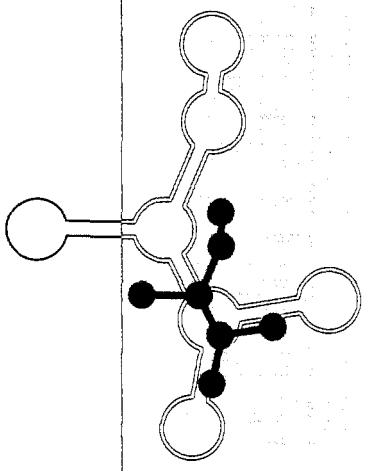
(in thousands)	2004	2003	2002
Other research and development:			
Impairment charge	$ —	$ 2,358	$ —
Realization of bank guarantee in connection with lease agreement	—	144	—
Severance charge	—	4	79
Total other research and development	—	2,506	79
Other general and administrative:			
Impairment charge	—	124	—
Realization of bank guarantee in connection with lease agreement	—	78	—
Severance charge	—	—	149
Accelerated depreciation	—	561	—
Total other general and administrative	—	763	149
Total	$ —	$ 3,269	$ 228

NOTE 13 - SUBSEQUENT EVENTS (UNAUDITED)

In January 2005, the Company announced that the Collaborative Study Group (CSG) recommended that it proceed to the Phase III portion of its Phase II/III clinical program of KRX-101 for the treatment of diabetic nephropathy, as planned. This recommendation was based on the completion, by an independent Data Safety Monitoring Committee, or DSMC, on January 4, 2005, of a safety evaluation of the first interim analysis from the approximately 150-patient, randomized, double-blind, placebo-controlled Phase II clinical trial of KRX-101, and an efficacy assessment of the same data set conducted by the CSG.

Pursuant to this recommendation, and subject to the Company's successful finalization of its clinical plan with the FDA, the Company expects to commence its pivotal program, including both Phase III and Phase IV studies for KRX-101, in the first half of 2005. The clinical plan to support an NDA for KRX-101 under Subpart H (accelerated approval) as discussed with the FDA consists of: (i) a Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria; (ii) supportive data from previous clinical studies; and (iii) substantial recruitment into the Company's Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. As part of the Company's commitment to the FDA, it plans to commence the Phase IV trial at approximately the same time as the start of the Phase III trial.

The KRX-101 Phase II/III clinical program is being conducted by the CSG, the world's largest standing renal clinical trial group, whose execution of the ACE Inhibition trial in Type 1 Diabetic Nephropathy and the trial of Irbesartan (an A2 Receptor Blocker or ARB) in Type 2 Diabetic Nephropathy (I.D.N.T.) both led to FDA approval and the recommendation of these agents as standards of care by the American Diabetes Association.



SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KERYX BIOPHARMACEUTICALS , INC .

Date: March 14, 2005

By: /s/ Michael S. Weiss
Michael S. Weiss
Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michael S. Weiss and Ron Bentsur, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 14, 2005, and in the capacities indicated:

Signatures	Title
/s/ Michael S. Weiss Michael S. Weiss	Chairman and Chief Executive Officer (principal executive officer)
/s/ Ron Bentsur Ron Bentsur	*Vice President Finance and Investor Relations* (principal financial and accounting officer)
/s/ I. Craig Henderson, M.D. I. Craig Henderson, M.D.	President and Director
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director
/s/ Lawrence Jay Kessel, M.D. Lawrence Jay Kessel, M.D.	Director
/s/ Peter Salomon, M.D. Peter Salomon, M.D.	Director
/s/ Eric A. Rose, M.D. Eric A. Rose, M.D.	Director
/s/ Lindsay A. Rosenwald, M.D. Lindsay A. Rosenwald, M.D.	Director

CERTIFICATION OF PERIODIC REPORT

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Weiss, certify that:

1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

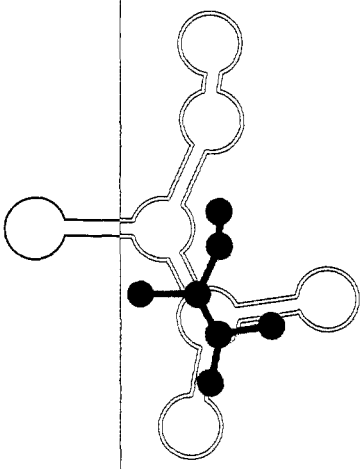
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2005

/s/ Michael S. Weiss
Michael S. Weiss
Chief Executive Officer
(Principal Executive Officer)



CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ron Bentsur, certify that:

1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2005

/s/ Ron Bentsur
Ron Bentsur
Vice President, Finance and Investor Relations
(Principal Financial and Accounting Officer)

BOARD OF DIRECTORS

Michael S. Weiss
Chairman and Chief Executive Officer

I. Craig Henderson, M.D.
President

Malcom Hoenlein
Executive Vice Chairman of the Conference of Presidents of Major American Jewish Organizations

Lawrence J. Kessel, M.D.
President of Lawrence J. Kessel, MD & Associates, PC

Eric A. Rose, M.D.
Director of Surgical Services and Surgeon-in-Chief at Columbia-Presbyterian Medical Center of New York-Presbyterian Hospital.

Lindsay A. Rosenwald, M.D.
Chairman of Paramount Capital, Inc.

Peter Salomon, M.D.
Principal, Gastroenterology Associates of South Florida

EXECUTIVE OFFICERS

Michael S. Weiss
Chairman and Chief Executive Officer

I. Craig Henderson, M.D.
President

Ron Bentsur
Vice President, Finance and Investor Relations

CORPORATE OFFICES

750 Lexington Ave.
20th Floor
New York, NY, 10022

TRANSFER AGENT & REGISTRAR

American Stock Transfer
& Trust Company
59 Maiden Lane, Plaza Level
New York, NY 10038

CORPORATE COUNSEL

Alston & Bird LLP
New York, NY

INDEPENDENT AUDITORS

KPMG LLP
New York, NY

10K AVAILABLE

A copy of the 2004 Annual Report for Keryx Biopharmaceuticals, Inc. as filed with the Securities and Exchange Commission on Form 10-K is available without charge upon written request. Please direct request to:

Ron Bentsur
Vice President, Finance and Investor Relations
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue, 20th Floor
New York, NY 10022

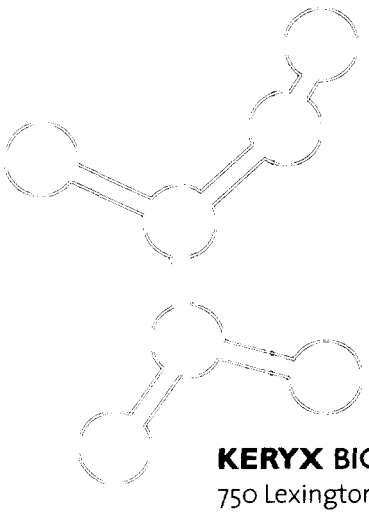
COMMON STOCK AND DIVIDEND INFORMATION

The Company's common stock is publicly-traded on the Nasdaq National Market under the symbol "KERX". The following table sets forth, for the period indicated, the high and low sale prices per share of the Company's common stock as reported by the Nasdaq National Markets.

2004 Quarter	High	Low
First	$ 15.42	$ 4.59
Second	19.07	10.57
Third	12.90	7.13
Fourth	13.80	9.65

As of March 21, 2005, there were approximately 63 record holders of our common stock. The Company has not paid dividends on its common stock. The Company anticipates it will continue to reinvest earnings to finance future growth, and therefore does not intend to pay dividends in the foreseeable future.

Design: Jason and Jason Visual Communications



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